REMARKS

Claims 20-32 are currently pending. Claims 31-32 have been canceled. New claims 33-54 have been added. Thus, upon entry of this amendment, claims 20-30 and 33-54 will be pending.

I. Drawings

Figures 1 and 2, which are incorporated by reference to the parent application, are enclosed herewith for inclusion in the specification. See Exhibit 1.

II. Written Description Rejection

The examiner objects to claim 20 reciting a mixture of polypeptides that is non-uniform with respect to "constitution." Applicants respectfully disagree that this term is unsupported by the specification in view of its ordinary meaning, as set forth in Applicants' previous response. Nonetheless, to expedite allowance, Applicants have amended claim 20 by replacing "constitution" with "sequence," which is a synonymous, non-narrowing term in the context of the specification.

The molecular weight recitation of "about 4 to about 9 kilodaltons" is supported, for example, at p. 2, ll. 18-20 and p. 9, l. 4. The recitation of "about 5 to about 9 kilodaltons" is supported, for example, at p. 9, l. 4.

The examiner states that no support is seen for the specific recitation of a molecular weight "substantially as depicted in the curves of Figure 1 or Figure 2 in which the average molecular weight is about 7.7 kDa." The principal support for this recitation is the figures, which have been incorporated into the specification. In addition, the term "substantially" is an appropriate term of approximation for claiming the curves of the figures for the reasons set forth in section IV, below.

Applicants therefore respectfully request withdrawal of the rejections for lack of written description.

Amendments to the Drawings:

Please add Figures 1 and 2 (attached as Exhibit 1).

III. Enablement Rejection

The examiner acknowledges that the specification is enabling for the use of "copolymer-1", but asserts that it is not enabling for "polypeptides composed of glutamic acid, lysine, alanine and tyrosine." Applicants respectfully disagree. However, to expedite prosecution, Applicants have amended the claims to recite "copolymer-1", the meaning of which is explained below.

The term "copolymer-1," as used in the specification and in the art, refers to a mixture of polypeptides of glutamic acid, lysine, alanine and tyrosine, but is not limited to a specific average molecular weight. In the specification of the pending application, in one instance, citing Teitelbaum et al., Eur. J. Immunol., 1:242-48 (1971), "copolymer-1" refers to a mixture of polypeptides of glutamic acid, lysine, alanine and tyrosine having a molar ratio of about 2 : 4.5 : 6 : 1 and an average molecular weight of about 23 kDa. However, in another instance, the term "copolymer-1" refers to a mixture of polypeptides having a lower average molecular weight, such as the "[f]our batches of copolymer-1, with average molecular weight between 6,250 - 14,500" described in Example 2 of the specification. Thus, "copolymer-1" is not limited to a specific molecular weight.

In addition, the term "copolymer-1" is not limited to a specific molar ratio of amino acids. The molar ratio of the polypeptides of "copolymer-1" varies slightly based on the particular batch and the particular analytical methodology used. In Teitelbaum, for example, two batches of copolymer-1 were prepared at the Weizmann Institute and, using a Beckman-Spinco automatic amino acid analyzer after acid hydrolysis, were determined to contain glutamic acid, lysine, alanine and tyrosine in a molar ratio of either 1.9 : 4.7 : 6.0 : 1.0, or 2.1 : 4.2 : 6.7 : 1.0, respectively. In Bornstein et al., "Clinical Experience with COP-1 in Multiple Sclerosis", N. Engl. J. Med., 317(7):408-14 (1987), three batches of copolymer-1 were obtained from the Weizmann Institute: batch nos. 320, 340 and 400. Citing Teitelbaum, Bornstein states that these three batches contain glutamic acid, lysine, alanine and tyrosine in a molar ratio of 1.9 : 4.7 : 6.0 : 1.0. However, when these batches were retested using total amino acid analysis, a molar ratio of 1.9 : 4.0 : 6.0 : 1.0, or 1.8 : 3.9 : 5.7 : 1.0, or 1.9 : 4.0 : 6.3 : 1.0, respectively, was obtained. Thus, "copolymer-1" does not refer to a specific molar ratio of amino acids.

IV. Indefiniteness Rejections

According to the examiner, the term "constitution" is unclear. For the reasons discussed above, "constitution" has been replaced in the claims by "sequence."

According to the examiner, the term "average molecular weight" is indefinite. Applicants respectfully disagree. One of ordinary skill in the art, upon reviewing the specification, would understand that "average molecular weight" refers to the molecular weight at the peak of the molecular weight distribution curve shown in Figure 1, which is "% of the total mass" versus "molecular weight." As shown in Figure 1, the "average molecular weight" is 7.7 kDa for the separated copolymer-1 ("Batch A") described in Example 1, and 12.0 kDa for the unseparated copolymer-1.

Claims 22 and 27 have been rejected as indefinite in reciting various percentages. Although Applicants respectfully disagree, the phrase "on a molar fraction basis" has been added to these claims. One of ordinary skill in the art would readily recognize that the percentages are molar fractions based on the descriptions in the specification. The table in Example 2, for instance, refers to the "% of species", which would be understood to be a molar fraction.

According to the examiner claim 30 is indefinite for reciting a molecular weight distribution "substantially" as depicted in the curves of Figure 1 or Figure 2. Applicants respectfully disagree. The term "substantially" is definite and appropriate here because a curve based on data points is inherently and inevitably variable to some small degree, and one of ordinary skill in the art would know what "substantially as depicted in the curves" means. See, e.g., MPEP § 2173.05(b)(D); Andrew Corp. v. Gabriel Elecs., Inc., 847 F.2d 819, 821 (Fed. Cir. 1988) (holding a claim not indefinite for reciting an antenna "which produces *substantially equal* E and H plane illumination patterns") (courtesy copy enclosed -- see Exhibit 2).

V. Clinical Trials

Applicants have disclosed to the Patent Office, *inter alia*, two clinical trials: "Clinical Trial Protocol No. 9001; first patient enrolled October 23, 1991" and "Clinical Trial Protocol No. 9002; first patient enrolled June 17, 1993," hereinafter referred to as "9001" and "9002",

respectively. These clinical trials were not public uses of the invention. They were experiments related to the development of the invention.

Subsequent to the Third Preliminary Amendment filed April 7, 2004, the Federal Circuit decided SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004) (hereinafter referred to as "SKB") (courtesy copy enclosed -- see Exhibit 3). The court held, *inter alia*, that a clinical trial in that case was not an experimental use of the invention, but rather a public use under 35 U.S.C. § 102(b). In that case, however, the invention was simply a chemical compound (the entire claim reads "Crystalline paroxetine hydrochloride hemihydrate") "without further limitation regarding efficacy, commercial use, or pharmaceutical viability." Id. at 1318. Based on this claim construction, the court held that the patentee's clinical trial was not a test on claimed features and therefore did not negate a public use. Id. at 1320. The Federal Circuit carefully distinguished narrower claims in the patent which were not asserted in the litigation, stating that clinical trials "may serve to negate a public use bar with regard to the inventions claimed in the more specific claims of the '723 patent." Id. Claim 5 of the '723 patent, for example, is limited to "anti-depressant" pharmaceutical compositions containing "an effective anti-depressant amount of" crystalline paroxetine hydrochloride hemihydrate, and claim 6 is limited to methods of treating depression by administration of "an effective amount" of crystalline paroxetine hydrochloride hemihydrate. *See* U.S. Pat. No. 4,721,723 (courtesy copy enclosed -- see Exhibit 4).

In contrast to the single claim at issue in SKB, Applicants have amended the pending claims to make it even more clear that clinical trials 9001 and 9002 were experimental uses that negate a finding of a public use under 35 U.S.C. § 102(b). The claims are limited to copolymer-1 which is "suitable for treating multiple sclerosis." In SKB, the court noted that an experimental use is one that "improves or verifies a feature [express or] inherent in the express claims of the invention." Id. at 1319. One purpose of clinical trial 9001 was to verify that an improvement in a copolymer-1 composition, reducing toxicity by lowering the average molecular weight, did not diminish or negate the effectiveness of the composition in treating multiple sclerosis. Stark Declaration, ¶ 4 (see Exhibit 5). One purpose of clinical trial 9002 was to collect and verify the

long-term safety of the improved copolymer-1 composition. Stark Declaration, ¶ 5. Thus, clinical trials 9001 and 9002 were necessary to verify the efficacy and pharmaceutical viability of the claimed invention. Stark Declaration, ¶ 6.

VI. Conclusion

Applicants believe that all of the pending claims are in condition for allowance. Any questions should be directed to the undersigned at the telephone number listed below.

Respectfully submitted,

Date: 12/1/04

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United States Court of Appeals,
Federal Circuit.

ANDREW CORPORATION, Plaintiff-Appellant,
v.
GABRIEL ELECTRONICS, INC., Defendant/Cross-Appellant.

Appeal Nos. 86-1689, 86-1690 and 87-1193.

May 25, 1988.

Appeal and cross appeal were taken from two judgments of the United States District Court for the District of Maine, Gene Carter, J., finding one patent invalid for indefiniteness, but infringed if valid, and holding another patent not infringed. The Court of Appeals, Pauline Newman, Circuit Judge held that: (1) a patent for improvements in a horn reflector microwave antenna was not invalid for indefiniteness, even if the applicant used words such as "approach each other," "close to," "substantially equal," and "closely approximate," and even if the applicant did not specifically delineate the point in which infringement started; (2) that patent was infringed under the doctrine of equivalents; and (3) the "isolation of the reflector assembly" language was a critical limitation on the competitor's patent claims and, therefore, that antenna was not literally infringed or infringed under the doctrine of equivalents by an antenna in which isolation did not exist.

Affirmed in part, reversed in part, and remanded.

Archer, Circuit Judge, filed a concurring opinion.

West Headnotes

[1] Patents 99
291k99 Most Cited Cases
Patent for improvements in horn reflector microwave antenna was not rendered indefinite by use of terms such as "approach each other," "close to," "substantially equal," and "closely approximate," with reference to horizontal and vertical distribution of microwave energy outside main beam. 35 U.S.C.A. § 112.

[2] Patents 99
291k99 Most Cited Cases
Claims for patent covering improvements in horn reflector microwave antenna were not fatally indefinite for failure to delineate specific point at which infringement would start and for failure of that point to correspond to unexpected change in properties. 35 U.S.C.A. § 112.

[3] Patents 16.1
291k16.1 Most Cited Cases
Patentee may set metes and bounds of that which is sought to be patented, and it is not material whether phenomena just outside these claims limits are qualitatively different from that which is claimed; patentee is not required to show that some technological discontinuity exists between claimed invention and subject matter just outside the claims, but only that claimed subject matter would have been nonobvious in view of prior art. 35 U.S.C.A. § 103.

[4] Patents 101(3)
291k101(3) Most Cited Cases
Law imposes no obligation on patent applicant to determine what is going on in technological gap between claimed invention and prior art, or to set claim limits at precise technological edge of invention. 35 U.S.C.A. § 103.

[5] Patents 97
291k97 Most Cited Cases
Alleged infringer failed to prove by clear and convincing evidence that patent applicant withheld material references from patent examiner, for purposes of determining whether patent for the improvements in horn reflector microwave antenna was unenforceable for inequitable conduct.

[6] Patents 314(1)
291k314(1) Most Cited Cases
To decline to decide issue of literal patent infringement when conflicting expert evidence appears to be counterbalancing, solely because subject matter is technically complex, would defeat party with burden of proof, without fair hearing.

[7] Patents 168(2.1)
291k168(2.1) Most Cited Cases
(Formerly 291k168(2))
Purpose of amendment of claim must be taken into account when considering prosecution history estoppel.

[8] Patents 237
291k237 Most Cited Cases
Accused horn reflector microwave antennas functioned in substantially the same way, to achieve substantially the same result as claimed antennas and, therefore, accused antennas infringed claimed

antennas under doctrine of equivalents.

[9] **Patents** 234
291k234 Most Cited Cases
"Isolation of the reflector assembly" was critical limitation in patent claims for horn reflector microwave antenna and, therefore, accused antenna, in which neither isolation nor equivalent was present, did not infringe patent.

Patents 328(2)
291k328(2) Most Cited Cases
3,305,870. Cited.

Patents 328(2)
291k328(2) Most Cited Cases
3,550,142. Not infringed.

Patents 328(2)
291k328(2) Most Cited Cases
4,410,892. Valid and infringed.

***820** Stephen G. Rudisill, Arnold, White & Durkee, Chicago, Ill., argued for plaintiff-appellant.

Charles Pfund, Dike, Bronstein, Roberts, Cushman & Pfund, Boston, Mass., argued for defendant/cross-appellant. With him on the brief was Robert M. Asher.

Before FRIEDMAN, NEWMAN, and ARCHER, Circuit Judges.

PAULINE NEWMAN, Circuit Judge.

Andrew Corporation (Andrew) and Gabriel Electronics, Inc. (Gabriel) appeal and cross-appeal two final judgments of the United States District Court for the District of Maine. The court held [FN1] Andrew's U.S. Patent No. 4,410,892 (the Knop patent) invalid for indefiniteness, but if valid infringed by Gabriel. The court's second judgment [FN2] held Gabriel's U.S. Patent No. 3,550,142 (the Dawson patent) not infringed by Andrew. We reverse the judgment of invalidity of the Knop patent and affirm the other aspects of both judgments.

FN1. *Andrew Corp. v. Gabriel Electronics, Inc.*, No. 83-0372-P (D.Me. August 1, 1986).

FN2. *Andrew Corp. v. Gabriel Electronics, Inc.*, 2 USPQ2d 1792 (D.Me.1987) [available on WESTLAW, 1987 WL 14966].

Background

Both the Knop and the Dawson patents relate to improvements in horn reflector microwave antennas used in long distance telephone and data communication networks. As described by the district court, a horn reflector antenna generally is constructed of an inverted vertical "feed" cone and a horizontal cylinder, which intersect at right angles. The microwave beam enters the feed cone vertically from the apex of the cone; an angled paraboloidal reflector catches the unfocused beam as it rises, focuses it into a coherent beam, and reflects it out the horizontal cylinder and on to the next antenna in the network.

The performance of such antennas is evaluated using the standard criteria of "gain" and "pattern". "Gain" refers to the strength of the focused beam relative to the original unfocused beam; higher gain allows transmission over longer distances. "Pattern", or "Radiation Pattern Envelope" ("RPE"), refers to the distribution of microwave energy outside the main beam in what are referred to as "sidelobes".

These patterns are measured in both the horizontal ("E-plane") and the vertical ("H-plane") directions. Normally, the E-plane has more energy distributed outside the main beam. This is referred to as having "higher sidelobes" or "a wider pattern", and results in unwanted interference with nearby antennas. The overall performance of an antenna is measurable by the E-plane and H-plane patterns.

THE KNOP PATENT

The Knop patent specification describes a horn reflector antenna that reduces interference ***821** with other antennas without significant loss of gain. This improved result is obtained by placing absorber material deep inside the conical feed horn. The use of absorber material had been shown in the prior art, placed in the first few inches of the conical feed horn to dampen stray radiation. According to the prior art, placing absorber material deeper into the cone causes unsatisfactory loss of gain. Knop teaches that this deep absorber acts by reducing the width of the E-plane RPE without significantly affecting the quality of the H-plane RPE, thereby improving overall performance of the antenna.

Indefiniteness--35 U.S.C. § 112
A

[1] The district court held the Knop patent claims invalid, stating that terms in the claims such as "approach each other", "close to", "substantially equal", and "closely approximate", with reference to

the E-plane and H-plane RPEs, were too vague to satisfy the requirement of definiteness stated in 35 U.S.C. § 112. [FN3] One or more of these terms appears in each of the claims, as illustrated in the following independent and dependent claims:

> FN3. 35 U.S.C. § 112 ¶ 2: The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. A conical horn-reflector antenna comprising the combination of:
a paraboloidal reflector forming a paraboloidal reflecting surface for transmitting and receiving microwave energy,
a smooth-walled conical feed horn for guiding microwave energy from the focus of said paraboloidal reflecting surface to said reflector, and
a lining of absorber material on the inside wall of the horn for reducing the width of the RPE in the E plane of the antenna without significantly increasing the width of the RPE in the H plane, said absorber increasing the Eigen value E and the spherical hybridicity factor Rs sufficiently to cause the E plane and H plane RPEs *to approach each other.*

3. A conical horn-reflector antenna as set forth in claim 2 which produces *substantially equal* E and H plane illumination patterns.

6. A method as set forth in claim 5 wherein said lining of absorber material increases the taper of the field distribution along the radii of said horn in the E plane to *closely approximate* the taper of the field distribution along the radii of said horn in the H plane. [emphases added]

The criticized words are ubiquitous in patent claims. Such usages, when serving reasonably to describe the claimed subject matter to those of skill in the field of the invention, and to distinguish the claimed subject matter from the prior art, have been accepted in patent examination and upheld by the courts. As this court put it in *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546-47, 221 USPQ 1, 7 (Fed.Cir.1984):

> Beckman attacks the claims as indefinite, primarily because "close proximity" is not specifically or precisely defined. As stated in the district court's Memorandum Decision, "to accept Beckman's contention would turn the construction of a patent into a mere semantic quibble that serves no useful purpose."

In *Rosemount* the district court found that " 'close proximity' is as precise as the subject matter permits". *Id.* In *Seattle Box Co. v. Industrial Crating & Packing*, 731 F.2d 818, 826, 221 USPQ 568, 573-74 (Fed.Cir.1984) (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed.Cir.1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984)), the court remarked that "substantially equal" is a term of degree, and that its acceptability depends on "whether one of ordinary skill in the art would understand what is claimed ... in light of the specification", even if experimentation may be needed.

In *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, No. 87-1296, 842 F.2d 1275, 1280, 6 USPQ2d 1277, 1282 (Fed.Cir.1988), this court stated that an "imprecise claim ***822** limitation, such as the phrase 'about 100% per second' " does not impart invalidity to the claims, but is to be considered in determination of infringement. *See also Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 95 (Fed.Cir.1986) ("the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more"), *cert. denied*, --- U.S. ----, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987); *Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed.Cir.), *cert. dismissed*, 474 U.S. 976, 106 S.Ct. 340, 88 L.Ed.2d 326 (1985):

> "If the claims, read in the light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more."

(quoting *Georgia-Pacific Corp. v. United States Plywood Corp.*, 258 F.2d 124, 136, 118 USPQ 122, 132 (2d Cir.), *cert. denied*, 358 U.S. 884, 79 S.Ct. 124, 3 L.Ed.2d 112 (1958)).

The Manual of Patent Examining Procedure instructs examiners in a similar vein. *See* MPEP § 706.03(d):

> [An examiner] should allow claims which define the patentable novelty with a *reasonable* degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. [emphasis in original]

Andrew asserted that the Knop claims could not reasonably be expressed more precisely; and indeed the court found that it "became very clear during trial ... that curves showing RPEs for horn antennas will never be identical". Words similar to those used in the Knop claims appear in prior art patents that were

of record in the district court, dealing with similar technology. For example, claim 1 of U.S. Patent No. 3,305,870 to Webb describes a "radiation pattern whose magnitudes in both the E and H planes are substantially equal".

Neither the record nor the law supports Gabriel's position that one of ordinary skill in the art would not know when the RPEs were "substantially equal" or "closely approximate". The district court's ruling is contrary to authority, and the holding of invalidity on this ground is reversed.

B

[2] The district court observed that the RPEs change gradually with increased depth of absorber in the cone. The court held that the claims must specifically delineate the point at which infringement starts, and that if such point does not correspond to an unexpected change in properties, the claims are fatally flawed under 35 U.S.C. § 112. The court said:

> There is no unexpected change in the E-plane at any of the levels of absorber which gives a clue to what is intended by the patent claims. The choice of a point beyond which there is infringement, therefore, is arbitrary and the point unforeseeable. [footnote omitted]

The district court held that the outer limit of the claim scope must coincide precisely with the point at which the claimed invention comes into scientific being. The court referred to *Brown-Bridge Mills, Inc. v. Eastern Fine Paper, Inc.*, 700 F.2d 759, 763, 217 USPQ 651, 655 (1st Cir.1983), which quoted with approval the holding originating in *Kwik-Set, Inc. v. Welch Grape Juice Co.*, 86 F.2d 945, 947, 32 USPQ 104, 106 (2d Cir.1936) that "It is only where the selected [i.e., claimed] point corresponds with the physical phenomenon and the patentee has discovered the point at which that physical phenomenon occurs that the maintenance of a patent monopoly is admissible."

This erroneous theory would prevent a patentee from obtaining claims that do not coincide with, or claim less than, the exact point at which a change in the physical phenomenon occurs; it would require the patentee always to discover that point, no matter how prolonged or expensive the additional research; and would bar patent ***823** protection when the change is by nature gradual or incremental at its transition, whether or not it is unobvious in view of the prior art.

Patentability is not measured against the closest point on the road to invention. Much technological change that meets the criterion of unobviousness, when viewed in light of the prior art, has a fuzzy boundary at its point of origin. Technological differences from prior art usually become more pronounced with distance from the boundary, but the changes may become manifest gradually. Indeed, the location of the boundary may well change with the available precision of measurement.

[3] It is the prior public knowledge--the "prior art"--by which patentability is tested. A patentee may set the metes and bounds of that which is sought to be patented, and it is not material whether the phenomena just outside these claim limits are qualitatively different from that which is claimed. The patentee is not required to show that some technological discontinuity exists between the claimed invention and the subject matter just outside the claims, but only that the claimed subject matter would have been nonobvious in view of the prior art. 35 U.S.C. § 103.

[4] The law imposes no obligation on a patent applicant to determine what is going on in the technological gap between the claimed invention and the prior art, or to set the claim limits at the precise technological edge of the invention. A claim is not fatally indefinite for failing specifically to delineate the point at which the change in physical phenomenon occurs. See, for example, the extensive body of case law holding that a patentee may claim less than the entire invention:

> Nothing is better settled in the law of patents than that the patentee may claim the whole or only a part of his invention, and that if he only describe and claim a part, he is presumed to have abandoned the residue to the public.

McClain v. Ortmayer, 141 U.S. 419, 423-24, 12 S.Ct. 76, 77, 35 L.Ed. 800 (1891).

To the extent that *Brown-Bridge* may be read as holding, as the district court appears to have believed, that a claim is invalid unless it sets as a limitation the exact technological border of the invention, we expressly reject that holding. [FN4] The district court's judgment of invalidity on this ground is reversed.

> FN4. The case authorities relied on in *Brown-Bridge v. Kwik-Set* and *Helene Curtis Indus. v. Sales Affiliates*, 233 F.2d 148, 154, 109 USPQ 159, 163-64 (2d Cir.1956), do not support the application that the district court gave them. In both

> *Kwik-Set* and *Helene Curtis* the claim limitation fell in the midst of the prior art; for instance the claim in *Helene Curtis* was to an optimum range of a chemical property where the chemical was already known to have that property. *See also Dow Co. v. Halliburton Co.*, 324 U.S. 320, 65 S.Ct. 647, 89 L.Ed. 973 (1945), which held on similar facts that the claimed range must be proved critical in order to show "invention". These cases were all concerned with showing "invention" in light of prior art, rather than the § 112 issues here involved.

Obviousness and Enablement

Gabriel appeals the district court's judgment that the Knop patent had not been proved invalid for obviousness, 35 U.S.C. § 103, or for lack of enablement, § 112. We have considered all of the arguments on both sides, and conclude that the court did not err in holding that the presumption of validity concerning these issues had not been overcome by clear and convincing evidence. *See Hybritech Inc.*, 802 F.2d at 1375, 231 USPQ at 87 ("the presumption of validity goes to validity of the patent in relation to the patent statute *as a whole,* not just to non-obviousness") (emphasis in original).

Inequitable Conduct

[5] Gabriel asserted that Knop withheld material references from the patent examiner, thereby rendering the patent unenforceable for inequitable conduct. The district court determined that a European patent application which was disclosed to the patent examiner in a Rule 312 amendment, 37 C.F.R. § 1.312, was reasonably timely disclosed and was not material to the prosecution of the Knop patent. The court also found that a horn antenna that was in the ***824** applicant's possession was "disclosed generically in the patent application" and that there was no intent to withhold this information. None of these findings has been shown to be clearly erroneous. Both materiality and intent to withhold must be shown, before these elements can be balanced in determining whether the applicant was guilty of inequitable conduct in patent prosecution. *J.P. Stevens & Co. v. Lex-Tex Ltd.*, 747 F.2d 1553, 1560, 223 USPQ 1089, 1092 (Fed.Cir.1984), *cert. denied,* 474 U.S. 822, 106 S.Ct. 73, 88 L.Ed.2d 60 (1985).

We affirm the district court's conclusion that inequitable conduct has not been proved by clear and convincing evidence.

Infringement of the Knop Patent

Andrew asserted infringement of Knop claims 1, 2, 3, 5, and 6 by the Gabriel antenna, either literally or in terms of the doctrine of equivalents. The district court first considered Andrew's assertion of literal infringement.

Construing the claims in light of the prosecution history, the court concluded that the final phrase of all the independent claims

> said absorber increasing the Eigen value E and the spherical hybridicity factor Rs sufficiently to cause the E plane and H plane RPEs to approach each other

was a material limitation because it was added during prosecution. The court heard testimony on whether the absorber in the accused Gabriel antenna achieved this result. Two experts testified, one called by Gabriel and one by Andrew, taking contrary positions on this issue. The district court found both experts to be "competent" and "credible". The court stated that it could not decide between the opposing positions of the experts concerning the Eigen value and the spherical hybridicity, and that "the court has no basis for accepting either proposition over the other". The court thus concluded that the evidence was "in equipoise", and therefore that the plaintiff had not met its burden of proving infringement by preponderant evidence.

A true equipoise of evidence may indeed defeat the party with the burden of proof, *see Aero Spacelines, Inc. v. United States*, 530 F.2d 324, 332, 208 Ct.Cl. 704 (1976); *see also Wilson v. Omaha Indian Tribe*, 442 U.S. 653, 669, 99 S.Ct. 2529, 2538, 61 L.Ed.2d 153 (1979), but there is no authority for holding evidence to be in equipoise for the sole reason that the court could not decide between conflicting experts. We agree with the statement in *United States v. General Motors Corp.*, 561 F.2d 923, 933 (D.C.Cir.1977), *cert. denied,* 434 U.S. 1033, 98 S.Ct. 765, 54 L.Ed.2d 780 (1978):

> The mere fact that experts disagree does not mean that the party with the burden of proof loses. The finder of fact has to make the effort to decide which side has the stronger case. This can be based on the demeanor of the witnesses (if so, the trial judge should say so) or the intellectual strength of the evidence and arguments based thereon.

[6] Given the complexity of modern technology, it

may well happen that qualified experts will appear on both sides, that their testimony will conflict, and that the testimony or the technology or both of them will be difficult to understand. However, to decline to decide the issue when conflicting evidence appears to be counterbalancing solely because the subject matter is technically complex, will defeat the party with the burden of proof without fair hearing.

Such treatment would remove complex technological issues from the purview of justice; this can not reflect the correct judicial response to a world increasingly bound to technology. Thus we do not endorse in principle the district court's treatment of literal infringement. In this case, however, the issue of infringement was adequately resolved by the court's analysis in terms of the doctrine of equivalents.

The district court found that Gabriel's antenna infringed the Knop patent under the doctrine of equivalents, applying the classical analysis of *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 70 S.Ct. 854, 94 L.Ed. 1097, 85 USPQ 328 (1950). The court stated, "From exhibits produced at trial, and without necessarily understanding the mathematical explanation, ***825** the Court can see that both the [accused device and] Andrew's embodiment of the patent function in the same way." The court thus found that although it did not know the precise changes in the Eigen value and spherical hybridicity factors of the final clause of claim 1, equivalency had been established based on the similarities in structure and RPEs of the accused antenna and the patented antenna, which showed that the two antennas achieved the same results by the same means in the same way. Thus, although the court had found that the evidence as to the subject matter of the final phrase of the claim was inconclusive, the court stated:

> At trial, the Court was thoroughly persuaded that for all practical purposes the [accused device] produced virtually the same patterns as those produced by the [patented device].

The court concluded that

> by use of the same means, the [accused device] produces the same results in the same way as the invention described by the Knop patent.

The court, applying the doctrine of equivalents to the accused device in light of the claimed invention viewed as a whole, held that the accused device was within the ambit of the claim, despite the absence of preponderant evidence as to the final phrase when analyzed in isolation from the rest of the claim.

Gabriel argues that the doctrine of prosecution history estoppel requires that the limitation of the final claim phrase be affirmatively found in the accused device, and that it can not be inferred based on similarities in structure, way, and result. Gabriel argues that since the district court held itself incapable of finding this fact, infringement can not be found, even under the doctrine of equivalents.

The district court had held, responding to this argument by referring to the prosecution history, that "it seems more appropriate to characterize the [addition during examination of the final claim phrase] as a clarification of the function of the absorber in the cone". The court concluded that "where the amendments were made for the purposes of explication and clarity, the Court does not think it appropriate to invoke estoppel against the application of the doctrine of equivalents."

[7] The purpose of an amendment must be taken into account when considering prosecution history estoppel. *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1363, 219 USPQ 473, 481 (Fed.Cir.1983) ("Depending on the nature and purpose of an amendment, it may have a limiting effect within a spectrum ranging from great to small to zero"). *See also Moeller v. Ionetics, Inc.*, 794 F.2d 653, 659-60, 229 USPQ 992, 996-97 (Fed.Cir.1986) (amendment was not intended to limit, but "to 'particularly point out' the invention", quoting the examiner).

[8] We agree with the district court's determination that this amendment to the Knop claims did not bar application of the doctrine of equivalents. Relying on the totality of similarities between the accused device and the claimed structure, including the similarities in the RPEs that are referred to in the final phrase of the claims, the district court found that the accused antennas perform the same function in substantially the same way to achieve substantially the same result as the claimed device. No clear error having been shown, the district court's finding of infringement is affirmed.

THE DAWSON PATENT

[9] The court held that Gabriel's Dawson patent for a horn reflector microwave antenna was not literally infringed by the Andrew antenna since the claimed isolation of the reflector assembly was not literally present. *Andrew Corp. v. Gabriel Electronics, Inc.*, 2 USPQ2d 1792, 1793-94 (D.Me.1987) [available on WESTLAW, 1987 WL 14966]. The court also held that the patent was not infringed under the doctrine of

equivalents.

It was not contested that the "isolation of the reflector assembly" is a critical limitation in the Dawson patent claims. The accused Andrew device was tested to determine if isolation existed. The court reviewed ***826** these tests and the accompanying testimony, and held that neither isolation nor an equivalent was present. We discern no clear error in the court's analysis and reasoning, and affirm its decision of noninfringement of the Dawson patent.

Summary

The court's judgment of invalidity of the Knop patent due to claim indefiniteness is reversed. The holding of validity on all other grounds is affirmed.

The judgment that the Gabriel antenna infringes the Knop patent is affirmed; the matter is remanded for determination of damages.

The judgment of non-infringement of the Dawson patent is affirmed.

Costs

Costs in appeal and cross-appeal in favor of Andrew Corporation, the prevailing party.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

ARCHER, Circuit Judge, concurring.

I join the majority opinion, except for the section headed "Infringement of the Knop Patent." With regard to infringement of the Knop patent, there is no need to consider literal infringement because, as the majority determines, the district court did not clearly err in finding that the Gabriel antenna infringes the Knop patent under the doctrine of equivalents.

I would, nonetheless, add that the district court's determination that Andrew had failed to carry its burden of proving literal infringement by preponderant evidence was not improper in my view, albeit probably unnecessary in view of its finding of infringement under the doctrine of equivalents. I also consider unwarranted the majority's criticism of the district court for finding the evidence on literal infringement to be in "equipoise" where, according to the district court, the critical "evidence of the opposing experts was directly contradictory" and presented "no basis for accepting either proposition over the other."

847 F.2d 819, 56 USLW 2736, 6 U.S.P.Q.2d 2010

END OF DOCUMENT

H
Briefs and Other Related Documents

United States Court of Appeals,
Federal Circuit.

SMITHKLINE BEECHAM CORPORATION and Beecham Group, P.L.C., Plaintiffs-Appellants,
v.
APOTEX CORP., Apotex, INC., and Torpharm, Inc., Defendants-Cross Appellants.

Nos. 03-1285, 03-1313.

April 23, 2004.

Background: Pharmaceutical drug manufacturer sued generic drug manufacturer for infringement of patent for active ingredient in antidepressant drug. The United States District Court for the Northern District of Illinois, Richard A. Posner, Circuit Judge, Sitting by designation, 247 F.Supp.2d 1011, determined that the paroxetine hydrochloride anhydrate product produced by generic drug manufacturer, if construed so as to be sufficiently definite, would not infringe the patent, and cross-appeals were taken.

Holdings: The Court of Appeals, Rader, Circuit Judge, held that:
(1) patent claim identifying crystalline paroxetine hydrochloride (PHC) hemihydrate as active ingredient in antidepressant drug was not invalid for indefiniteness;
(2) patent was infringed by generic drug manufacturer's PHC anhydrate tablets, which contained trace amounts of PHC hemihydrate; but
(3) patentee's clinical trials constituted a public use, rendering patent claim invalid.
Affirmed.

Gajarsa, Circuit Judge, filed concurring opinion.

West Headnotes

[1] **Patents** 324.5
291k324.5 Most Cited Cases
Court of Appeals reviews patent claim construction without deference.

[2] **Patents** 324.55(5)
291k324.55(5) Most Cited Cases
Court of Appeals reviews measurement of the accused product or process against the patent claim as a question of fact.

[3] **Patents** 324.5
291k324.5 Most Cited Cases
Review of indefiniteness of patent claim proceeds as a question of law without deference. 35 U.S.C.A. § 112.

[4] **Patents** 165(4)
291k165(4) Most Cited Cases
Scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning.

[5] **Patents** 101(5)
291k101(5) Most Cited Cases

[5] **Patents** 101(6)
291k101(6) Most Cited Cases
To satisfy particularity requirement, patent claim, read in light of the specification, must apprise those skilled in the art of the scope of the claim; moreover, claims need not be plain on their face in order to avoid condemnation for indefiniteness, rather, what is required is that the claims be amenable to construction, however difficult that task may be. 35 U.S.C.A. § 112.

[6] **Patents** 101(6)
291k101(6) Most Cited Cases
Patent claim identifying crystalline paroxetine hydrochloride (PHC) hemihydrate as active ingredient in antidepressant drug was not invalid for indefiniteness; claim recited in clear terms a discernible chemical structure. 35 U.S.C.A. § 112.

[7] **Patents** 101(6)
291k101(6) Most Cited Cases
Test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention. 35 U.S.C.A. § 112.

[8] **Patents** 101(6)
291k101(6) Most Cited Cases
Even if a patent claim is broad enough to embrace undetectable trace amounts of the claimed invention, breadth is not indefiniteness. 35 U.S.C.A. § 112.

[9] **Patents** 250
291k250 Most Cited Cases
Patent claim identifying crystalline paroxetine

hydrochloride (PHC) hemihydrate as active ingredient in antidepressant drug was infringed by generic drug manufacturer's PHC anhydrate tablets, which contained trace amounts of PHC hemihydrate.

[10] Patents 314(5)
291k314(5) Most Cited Cases
Whether a patent is invalid due to public use is a question of law based on underlying questions of fact. 35 U.S.C.A. § 102(b).

[11] Patents 75
291k75 Most Cited Cases
For purposes of patent validity, "public use" includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor; therefore, public use statute erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation. 35 U.S.C.A. § 102(b).

[12] Patents 75
291k75 Most Cited Cases
For purposes of patent validity, experimental use negates public use bar; when proved, it may show that particular acts, even if apparently public in a colloquial sense, do not constitute a public use within the meaning of applicable statute, and thus operates to negate application of the public use bar. 35 U.S.C.A. § 102(b).

[13] Patents 81
291k81 Most Cited Cases
Once the challenger of the patent has proven by clear and convincing evidence that the invention was in public use before the critical date, the burden of production shifts to the patentee to provide sufficient evidence to create a genuine issue of material fact that the use qualifies as experimental; however, ultimate burden remains on the challenger to prove by clear and convincing evidence that the non-experimental use was public under applicable statute. 35 U.S.C.A. § 102(b).

[14] Patents 75
291k75 Most Cited Cases
An experimental use only negates a statutory public use bar when the inventor was testing claimed features of the invention. 35 U.S.C.A. § 102(b).

[15] Patents 75
291k75 Most Cited Cases
Clinical tests, which measured the efficacy and safety of the compound as an antidepressant, did not qualify as an experimental use to negate the statutory public use bar, since antidepressant properties of the compound were not claimed features; patent claim was defined as crystalline paroxetine hydrochloride (PHC) hemihydrate compound without further limitation regarding efficacy, commercial use, or pharmaceutical viability. 35 U.S.C.A. § 102(b).

Patents 328(2)
291k328(2) Most Cited Cases
4,721,723. Invalid.

***1308** Ford F. Farabow, Jr., Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., of Washington, DC, argued for plaintiffs-appellants. With him on the brief were Robert D. Bajefsky, Howard W. Levine, Scott J. Popma, Jennifer S. Swan, Aaron M. Raphael.

Deanne M. Mazzochi, Lord, Bissell & Brock, of Chicago, Illinois, argued for defendants-cross-appellants. With her on the brief were Hugh L. Moore, Keith D. Parr, Hugh S. Balsam, and Kevin M. Nelson. Of counsel were Paul J. Molino, Scott B. Feder, and William A. Rakoczy.

Before RADER, BRYSON, and GAJARSA, Circuit Judges.

RADER, Circuit Judge.

Following a bench trial, the United States District Court for the Northern District of Illinois determined that the paroxetine hydrochloride anhydrate product produced by Apotex Corp., Apotex, Inc., and TorPharm, Inc. (collectively Apotex) will not infringe claim 1 of U.S. Patent No. 4,721,723 owned by SmithKline Beecham Corp. and Beecham Group, P.L.C. (collectively SmithKline). *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1052 (N.D.Ill.2003). Claim 1 of the '723 patent recites, in its entirety, "Crystalline paroxetine hydrochloride hemihydrate." Upon this court's revision of the trial court's erroneous claim construction, Apotex's product will infringe this claim. Nonetheless because the public use bar of 35 U.S.C. § 102(b) renders claim 1 of the '723 patent invalid, this court affirms the district court's judgment in favor of Apotex.

I.

In the late 1970s, a British company called Ferrosan invented a new class of compounds, including a compound that became known as paroxetine. *See* U.S. Patent No. 4,007,196. The '196 patent claims paroxetine and its salts and discloses their antidepressant properties. Ferrosan eventually developed a process to produce the crystalline hydrochloride salt of paroxetine, or paroxetine hydrochloride (PHC). In 1980, Ferrosan licensed the

'196 patent ***1309** and its other PHC-related technology to SmithKline. SmithKline began manufacturing PHC in its Harlow plant in England.

In March 1985, a chemist in SmithKline's Worthing, England laboratory, Alan Curzons, created a new crystalline form of PHC while attempting to improve PHC production. Curzons' test results established that the new product was the hemihydrous form of PHC (PHC hemihydrate), while Ferrosan's original form was anhydrous PHC (PHC anhydrate). PHC anhydrate comprises crystals of PHC without bound water molecules. PHC hemihydrate comprises PHC crystals with one bound water molecule for every two PHC molecules. PHC hemihydrate proved more stable and thus more easily packaged and preserved.

Further review of the SmithKline samples showed that the Harlow plant had unwittingly made PHC hemihydrate as early as December 1984. In May 1985, SmithKline began double-blind clinical tests in the United States to determine the safety and efficacy of PHC hemihydrate capsules to treat depression symptoms. In these clinical tests, the doctors and patients were aware of the drug being tested, but were not aware which patients were taking a placebo and which were taking the actual drug.

SmithKline filed a patent application in the British Patent Office on October 25, 1985 relating to "crystalline paroxetine hydrochloride, its preparation and its uses as a therapeutic agent." The British application identified the invention as both the hemihydrate and the anhydrate form of PHC, as well as mixtures that contain a major portion of either form. One year later, on October 23, 1986, SmithKline filed a U.S. application claiming priority to the British application that issued as the '723 patent in 1988. The '723 patent does not claim PHC anhydrate and does not claim mixtures of the two PHC forms. The only claim at issue in this case is claim 1, which reads, "Crystalline paroxetine hydrochloride hemihydrate."

In 1993, after completing the necessary FDA approval process, SmithKline placed its antidepressant drug with PHC hemihydrate as the active ingredient on the market under the name Paxil®. In 1998, TorPharm, Inc., an Apotex affiliate and manufacturer of Apotex's generic antidepressant, filed an Abbreviated New Drug Application (ANDA) with the FDA, under 21 U.S.C. § 355(j), seeking approval to market its own PHC antidepressant drug. Apotex identified the active ingredient in its antidepressant as PHC anhydrate. Apotex's ANDA included a paragraph IV certification, *see* 21 U.S.C. § 355(j)(2)(A)(IV), that indicated Apotex intended to market the drug before the expiration of the '723 patent because its drug would not infringe that patent.

In 1998, SmithKline initiated this infringement action against Apotex under 35 U.S.C. § 271(e)(2) on the basis of Apotex's ANDA filing. SmithKline alleges that Apotex's proposed drug will infringe claim 1 of the '723 patent. SmithKline does not allege that claim 1 of the '723 patent covers PHC anhydrate. After all, PHC anhydrate--the Ferrosan discovery--is prior art for the '723 patent. SmithKline asserts that Apotex will infringe by manufacturing PHC anhydrate tablets that necessarily contain, by a conversion process discussed below, at least trace amounts of PHC hemihydrate.

The parties filed various summary judgment motions, including cross motions for summary judgment that claim 1 of the '723 patent was invalid (or valid) under 35 U.S.C. § 102(b) for an impermissible public use. The § 102(b) motions acknowledged that the clinical trials occurred more than one year before SmithKline's filing ***1310** date for the '723 patent, but disputed whether those tests qualified for the experimental use negation. The district court denied Apotex's motion and granted SmithKline's motion, holding that the '723 patent was not invalid for public use under § 102(b). The district court reasoned that the clinical trials qualified as experimental uses. *See SmithKline Beecham Corp. v. Apotex Corp.*, 286 F.Supp.2d 925, 932- 38 (N.D.Ill.2001).

The district court then held a bench trial to determine the proper interpretation of claim 1 and resolve the remaining infringement and validity issues. On the question of claim construction, the district court limited claim 1 to PHC hemihydrate in commercially significant amounts. *SmithKline Beecham Corp.*, 247 F.Supp.2d at 1030. The trial record contained uncontested testimony that a PHC anhydrate-hemihydrate mixture would need to possess a percentage of PHC hemihydrate in the "high double digits" if the hemihydrate component were to contribute any commercial value. *Id.* The district court grafted that commercial significance into the claim and held that Apotex's proposed PHC drug will not infringe claim 1 of the '723 patent. The district court found, as a factual matter, that Apotex's PHC anhydrate tablets will not contain detectable or commercially significant amounts of PHC anhydrate and rejected SmithKline's evidence to the contrary. *Id.* at 1031- 39. The trial court also determined that

claim 1 is not invalid.

SmithKline contested the district court's claim interpretation noting that claim 1 is clear on its face and encompasses PHC hemihydrate in any amount, however small or insignificant. In rejecting that proposed claim interpretation, the district court also opined that SmithKline's proposed construction would render claim 1 indefinite. The district court reasoned that SmithKline's interpretation would place potential infringers in the untenable position of never knowing whether their product infringes because even a single undetectable crystal of PHC hemihydrate would infringe. *Id.* at 1029-30.

To show that manufacture of PHC anhydrate tablets necessarily creates PHC hemihydrate, SmithKline proffered expert testimony on the so-called "seeding" or "disappearing polymorph" theory. Under this theory, Ferrosan may have originally created a crystalline compound, namely PHC anhydrate, in a relatively unstable form. As Ferrosan and its successors improved the manufacturing and testing procedures for PHC, the compound "morphed" into a more pure and stable form, namely the PHC hemihydrate discovered in SmithKline's facilities. Once this new form or polymorph exists, SmithKline's experts explained, the general environment becomes "seeded" with crystals of the new polymorph. In this seeded environment, the old polymorph converts to the new polymorph upon its inevitable contact with seeds of the new polymorph. In other words, the creation of a pure version of the old polymorph becomes extremely difficult, if not impossible; the old polymorph has effectively disappeared and been replaced by the new.

SmithKline's experts applied the disappearing polymorph theory to show that Apotex's PHC anhydrate tablets inevitably convert to hemihydrate when combined with moisture, pressure, and practically ubiquitous PHC hemihydrate seeds. The district court found that SmithKline's evidence on seeding and the disappearing polymorph theory supported the inference that Apotex's PHC anhydrate tablets will contain at least trace, or undetectable, amounts of PHC hemihydrate. *Id.* at 1042-43. Thus, under SmithKline's claim construction, the district court held that ***1311** Apotex's PHC anhydrate drug would infringe claim 1 of the '723 patent. *Id.*

Alternatively, if claim 1 was construed to cover any amount of PHC hemihydrate and was, therefore, infringed, the district court purported to create a new equitable defense to infringement in favor of Apotex. *Id.* at 1043-45. Under this new defense, SmithKline was responsible for producing the hemihydrate, which, by virtue of SmithKline's disappearing polymorph theory, seeded the environment. Consequently, SmithKline caused the alleged infringement. The district court reasoned that Apotex should enjoy the right to practice the prior art by manufacturing PHC anhydrate. Accordingly, under its alternative equitable defense, the district court absolved Apotex of liability for the consequences of SmithKline's own conduct that rendered the practice of the prior art impossible without infringing the '723 patent. The district court also held that its inherent equitable powers and the equitable nature of injunctions in general placed the injunction mandated by 35 U.S.C. § 271(e)(4)(A) within the discretion of the district court. *Id.* at 1045-52.

SmithKline also sought to assert a claim of induced infringement against Apotex on the theory that anhydrate tablets convert to PHC hemihydrate in the stomach of a patient due to the increased humidity and pressure. The district court excluded SmithKline's evidence on this issue, finding that SmithKline would likely not meet its burden of showing "gastrointestinal infringement." *Id.* at 1014-15. Finally, the district court considered other alternative claim constructions, which would allow claim 1 to cover PHC hemihydrate in amounts detectable either by methods available at the time the '723 patent was filed or by any means that later became available. *Id.* at 1052. The record shows that SmithKline presented the results of tests on various samples of Apotex tablets. These tests showed PHC hemihydrate in the Apotex product. The district court rejected this evidence as unreliable, mainly because SmithKline's counsel excluded select tablets from the testing without reasonable explanation. *Id.* at 1032-42. The trial court found these excluded tablets to represent best the product Apotex would manufacture upon ANDA approval. *Id.* Accordingly, the district court held that SmithKline did not prove that Apotex's tablets will contain any detectable amount of PHC hemihydrate.

SmithKline presents five arguments on appeal. First, the district court erred in limiting claim 1 to commercially significant amounts of PHC hemihydrate. Second, contrary to the trial court's ruling, a claim construction that covers PHC hemihydrate in any amount does not render claim 1 indefinite. Third, the district court erred in creating an equitable defense to infringement based on SmithKline's contribution to causing the infringement. Fourth, the district court erred in

holding that the injunctive relief required under 35 U.S.C. § 271(e)(4) is within the district court's discretion. Fifth, the district court abused its discretion in excluding SmithKline's evidence of induced infringement.

In its cross-appeal, Apotex argues that the district court erred in granting summary judgment that SmithKline's clinical tests qualified as an experimental use. In particular, Apotex asserts that claim 1 of the '723 patent is invalid for public use under 35 U.S.C. § 102(b) as a matter of law. This court has jurisdiction over these appeals under 28 U.S.C. § 1295(a)(1).

II.

Standards of Review

This court reviews summary judgments without deference. *See* ***1312***Beech Aircraft Corp. v. EDO Corp.*, 990 F.2d 1237, 1245 (Fed.Cir.1993). Of course, a denial of summary judgment, by itself, is not a final judgment amenable to appeal like a grant of summary judgment. However, when both parties move for summary judgment, each motion "must be independently assessed on its own merit." *California v. United States*, 271 F.3d 1377, 1380 (Fed.Cir.2001). In such circumstances, this court determines whether summary judgment is appropriate under the standard rules of Fed.R.Civ.P. 56.

In this case, both parties sought summary judgment; the district court granted one and denied the other. Thus, the record may show that the parties have conceded, and the district court has found, that no material factual issues remain in dispute. *See Beech Aircraft*, 990 F.2d at 1245. If this court determines that no material facts remain in dispute, it may proceed to determine entitlement to judgment under the law. *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed.Cir.2001) ("[R]eversal is required if the district court 'engaged in a faulty legal analysis in applying the law to the facts and a correct application of the law to those facts might bring a different result.' ") (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 164 (Fed.Cir.1985)); *see also Anderson v. Liberty Lobby Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

This court reviews a district court's judgment, following a bench trial, for errors of law or clearly erroneous findings of fact. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1343-44 (Fed.Cir.2002). Patent infringement proceeds under a two-step analysis. First, the court interprets the claims to determine their proper scope and meaning. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc). Next, the court measures the accused product or process against the standard of the properly interpreted claims. *Id.*

[1][2][3] This court reviews claim construction without deference. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). This court reviews the second step, measurement of the accused product or process against the claim, as a question of fact. *See Allen Eng'g*, 299 F.3d at 1343-44; *Gen. Mills, Inc. v. Hunt-Wesson, Inc.*, 103 F.3d 978, 981 (Fed.Cir.1997). The review of indefiniteness under 35 U.S.C. § 112, paragraph 2, proceeds as a question of law without deference. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377 (Fed.Cir.2000); *Personalized Media Communications, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 702 (Fed.Cir.1998).

Factual Findings

As an initial matter, this court holds that the record supports the district court's factual findings. In particular, the district court did not clearly err in concluding that Apotex's PHC anhydrate product will include trace amounts of PHC hemihydrate based on the record evidence of seeding and disappearing polymorphs. *See SmithKline Beecham Corp.*, 247 F.Supp.2d at 1019-23.

The district court also did not clearly err in finding that Apotex's anhydrate product will not contain detectable quantities of PHC hemihydrate because SmithKline selectively tested the Apotex samples without explaining its reasons for excluding some Apotex products from the examination. Specifically, the district court's discretionary exclusion of SmithKline's unreliable evidence on this issue does not render the subsequent factual finding clearly erroneous. Accordingly, this court decides the legal issues in this ***1313*** appeal against the factual background as determined by the district court.

Claim Construction & Indefiniteness

Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention. *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1378 (Fed.Cir.2003); *Phillips Petroleum Co. v. Huntsman Polymers Corp.*, 157 F.3d 866, 871 (Fed.Cir.1998). This task requires

the court to place the claim language in its proper technological and temporal context. The best tools for this enterprise are the various forms of intrinsic evidence and, when appropriate, extrinsic evidence. *See Vitronics, Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). The intrinsic evidence, "i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history ... is the most significant source of the legally operative meaning of disputed claim language." *Id.*

Of course, at all times, the language of the claims governs their scope and meaning. *See Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1372 (Fed.Cir.2001). Unless the intrinsic evidence compels a contrary conclusion, the claim language carries the meaning accorded those words in the usage of skilled artisans at the time of invention. *See id.; Vitronics*, 90 F.3d at 1582.

As stated earlier, claim 1 of the '723 patent reads, "Crystalline paroxetine hydrochloride hemihydrate." This language is not ambiguous, but rather describes a very specific compound. The record repeatedly shows that artisans in this area of technology at the time of invention would have understood that the claim embraces PHC hemihydrate without further limitation.

The inquiry proceeds to the remainder of the intrinsic record to determine if the patent applicant gave these unambiguous words some unexpected definition. The district court limited claim 1 to commercially significant amounts of PHC hemihydrate. The trial court found support for this limitation in portions of the '723 patent that discuss the pharmaceutical and commercial properties of PHC hemihydrate. For example, the specification discusses the superior handling properties of the hemihydrate form that improve the manufacture of PHC. Those references, however, do not redefine the compound in terms of its commercial properties, but emphasize that the new compound exhibits favorable characteristics. A description of characteristics does not redefine a compound with an established and unambiguous structural definition.

Moreover, nothing in the '723 patent limits that structural compound to its commercial embodiments. Rather, the '723 specification discloses PHC hemihydrate as a compound without reference to its commercial applications. For example, the specification states that the "present invention provides crystalline paroxetine hydrochloride hemihydrate as a novel compound." '723 patent, col. 1, ll. 57-58. Furthermore, nothing in the prosecution history of the '723 patent defines the invention in terms of commercially significant quantities. Thus, reading claim 1 in the context of the intrinsic evidence, the conclusion is inescapable that the claim encompasses, without limitation, PHC hemihydrate--a crystal form of paroxetine hydrochloride that contains one molecule of bound water for every two molecules of paroxetine hydrochloride in the crystal structure.

[4] The district court openly discussed the policies that led to its insertion of commercially significant quantities as a limitation on the meaning of the claimed compound. The district court observed that a claim construction that covers trace ***1314** amounts of PHC hemihydrate would likely preclude attempts to make the prior art PHC anhydrate compound. After explaining the "*in terrorem* effect" of such a "broad" claim construction, the district court rejected the literal scope of claim 1 because it would produce "absurd results" and would "not serve any policy of patent law." Claim construction, however, is not a policy-driven inquiry. As stated earlier, it is a contextual interpretation of language. The scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning. *See Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed.Cir.1995) ("[I]t is well settled that no matter how great the temptations of fairness or policy making, courts do not redraft claims"). For this precise reason, this court has repeatedly stated that a court must construe claims without considering the implications of covering a particular product or process. *See NeoMagic Corp. v. Trident Microsys. Inc.*, 287 F.3d 1062, 1074 (Fed.Cir.2002); *SRI Int'l. v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1118 (Fed.Cir.1985).

The district court also justified its commercial-significance limitation to preserve the claim's validity in the face of a challenge to its definiteness under § 112, second paragraph. In essence, the district court considered the claim indefinite if construed to cover undetectable trace amounts of the PHC compound. In other words, the trial court feared that potential infringers would not be able to determine (and avoid) infringement if they cannot detect the claimed compound. *See Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469-70 (Fed.Cir.1993). This reasoning misses the proper purpose of the definiteness requirement.

[5][6] The second paragraph of § 112 requires the

specification of a patent to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2000). To satisfy this requirement, the claim, read in light of the specification, must apprise those skilled in the art of the scope of the claim. *See Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed.Cir.1993). Moreover, claims need not "be plain on their face in order to avoid condemnation for indefiniteness; rather, what [this court has] asked is that the claims be amenable to construction, however difficult that task may be." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed.Cir.2001). In this case, the claim covers a definite chemical structure. To a chemist in this field, this claim is plain on its face. Thus, claim 1 of the '723 patent cannot be invalid for indefiniteness under § 112.

In *Morton*, this court affirmed a district court's judgment of indefiniteness because "one skilled in the art could not determine whether a given compound was within the scope of the claims." *Morton*, 5 F.3d at 1470. Thus, the claims at issue were "not sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *Id.* The *Morton* case, therefore, does not hold that the inability to detect the claimed compound in the infringing device renders a compound claim indefinite. Rather, *Morton* stands for the unremarkable proposition that a compound claim, to be definite, must apprise a skilled artisan of the bounds of the claim. The record in *Morton* contained "considerable evidence showing that those skilled in the art could not make the claimed compounds using the procedures of the specification, and no evidence that such compounds even exist." *Id.* at 1469-70.

This case bears little similarity to *Morton*. In this case, claim 1 unambiguously ***1315** identifies the bounds of the claim. It states "Crystalline paroxetine hydrochloride hemihydrate." Thus, this claim recites in clear terms a discernible chemical structure. It would be difficult to imagine a more clear and definite claim.

[7][8] The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention. In this case, the problem for Apotex is that it cannot accurately ascertain the nature of its own product. The scope of this claim is clear; the infringement of the Apotex product is not. Even if a claim is broad enough to embrace undetectable trace amounts of the claimed invention, "[b]readth is not indefiniteness." *In re Gardner*, 57 C.C.P.A. 1207, 427 F.2d 786, 788 (CCPA 1970). Stated more precisely, this claim is neither broad nor narrow, but definitive of this particular chemical structure. For inventing and disclosing this structure, the inventor enjoys the exclusive right to practice that invention for the patent's limited term. Accordingly, claim 1, as construed above, is not indefinite under 35 U.S.C. § 112, second paragraph.

Infringement and Equity

[9] Having interpreted claim 1 to cover PHC hemihydrate without further limitation, this court turns to infringement. In anticipation of this very scenario, the district court performed a factual infringement analysis based on this correct claim construction. The district court held that the evidence showed that Apotex's PHC anhydrate tablets would contain trace amounts of PHC hemihydrate. As indicated above, the record supports this factual finding. This court, therefore, affirms the district court's finding that Apotex's product will infringe under this court's claim construction.

Because Apotex seeks to practice the prior art, and because that practice infringes, the next logical inquiry involves anticipation. That is, if the prior art infringes now, logically the prior art should have anticipated the claim before the filing of the '723 patent. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed.Cir.2001) (restating the axiom that "that which would literally infringe if later in time anticipates if earlier"). At trial, Apotex asserted that Ferrosan's process of making PHC anhydrate inherently resulted in trace amounts of the hemihydrate prior to the '723 patent and thus anticipated that patent. The district court, however, determined that Apotex did not present clear and convincing evidence of inherent anticipation. According to the district court's findings, "no one knows when the hemihydrate form of paroxetine came into existence, although it is a reasonable inference that it did not exist in a detectable amount until" SmithKline's "serendipitous" discovery. *SmithKline Beecham Corp.*, 247 F.Supp.2d at 1022, 1025. Apotex does not appeal that ruling.

SmithKline's disappearing polymorph theory makes its apparently inconsistent positions possible. On the one hand, SmithKline asserts that the creation of a

prior art compound will result in a product containing at least trace amounts of their patented compound. On the other hand, SmithKline contends that the creation of the prior art compound before SmithKline's discovery of its compound did not have the same result. For this reason, the district court was understandably uncomfortable about allowing claim 1 to embrace its literal scope. The district court feared such a construction would result in "a considerable extension in the effective patent term of paroxetine because it might become ***1316** difficult or even impossible to manufacture the pure anhydrous form after the Ferrosan patent expired." *Id.* at 1019. While these concerns are certainly legitimate, claim construction, as noted before, proceeds independent of its policy implications. Fortunately, the district court had the foresight to consider alternative analyses in this unique situation.

The district court, in its alternative infringement analysis, properly found infringement, but cabined the infringement with a new equitable defense. In short, the defense would apply where the patentee significantly contributed to causing the infringement. After all, SmithKline's creation of the hemihydrate form of PHC also created a seeded environment that, under the facts found by this district court, makes the practice of the prior art an infringement, while precluding operation of anticipation by inherency. In this unique and unprecedented circumstance, the trial court understandably reached out to find an equitable remedy to protect Apotex. In any event, notwithstanding the potential merit of a new equitable doctrine in this unprecedented instance, this court can resolve this case without its application because claim 1 is invalid for public use under 35 U.S.C. § 102(b). Accordingly, this court declines to address the trial court's proposed equitable defense.

The concurring opinion seeks to remedy the perceived inequity in this case by applying 35 U.S.C. § 101, arguing the subject matter of claim 1 does not cover patentable subject matter. Unfortunately, the concurrence confuses patent eligibility under § 101 with patentability under other provisions in the Patent Act, such as 35 U.S.C. § 102. The concurrence admits that PHC hemihydrate is a synthetic, man-made compound eligible for patent protection. In fact, the claimed invention is without question a "composition of matter" or an article of "manufacture" within the terms of § 101. Accordingly, the claimed invention represents subject matter eligible for patent protection under § 101. With that conclusion, the inquiry under § 101 ends.

The concurring opinion, however, would expand the subject matter eligibility analysis under § 101 to encompass some review of the scope of the claims. To the contrary, "[e]ither the subject matter falls within Section 101 or it does not." *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed.Cir.1991). The scope of the claims is not relevant to subject matter eligibility. Subject matter does not take on a different eligibility status with adjustments in the scope of the proposed claim. Patent eligibility under § 101 is simply not an issue in this case.

Public use-- § 102(b)

[10] A patent claim is not valid if "the invention was ... in public use ... in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2000). Whether a patent is invalid due to public use under § 102(b) is a question of law based on underlying questions of fact. *See 3M Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed.Cir.2002). Thus, without genuine factual disputes underlying the public use inquiry, the issue is ripe for judgment as a matter of law.

[11] In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 119 S.Ct. 304, 142 L.Ed.2d 261 (1998), the Supreme Court rejected the former "substantially complete under a totality of circumstances" test for the on sale bar under § 102(b) and adopted a two-prong test. That test bars a patent when the claimed invention, before the critical date, was the subject of a commercial offer for sale and was ready for patenting. *Id.* at 67, 119 S.Ct. 304. A similar analysis applies to the public use bar under § 102(b). Although the commercial sale ***1317** prong is inapplicable, "[p]ublic use under 35 U.S.C. § 102(b) includes any use of the *claimed invention* by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." *Netscape Communications Corp. v. Konrad*, 295 F.3d 1315, 1321 (Fed.Cir.2002) (emphasis added). Thus, § 102(b) erects a bar where, before the critical date, the invention was ready for patenting and was used by a person other than the inventor who is under no confidentiality obligation.

[12] "Experimental use negates public use; when proved, it may show that particular acts, even if apparently public in a colloquial sense, do not constitute a public use within the meaning of section 102." *Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1059 (Fed.Cir.1996) (citing *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed.Cir.1984)); *see also City of Elizabeth v. Am.*

Nicholson Pavement Co., 97 U.S. 126, 134, 24 L.Ed. 1000 (1877). The experimental use doctrine is not an "exception" to the public use bar because it does not shift the burden of proof from the accused infringer to the patentee. Rather, it operates to negate application of the public use bar. *See EZ Dock, Inc. v. Schafer Sys., Inc.*, 276 F.3d 1347, 1351-52 (Fed.Cir.2002) ("This court has repeatedly stressed that evidence of experimental use does not give rise to a free-standing doctrinal exception to statutory bars, but instead operates to negate application of section 102(b)").

[13] In other words, once the challenger of the patent has proven by clear and convincing evidence that the invention was in public use before the critical date, the burden of production shifts to the patentee to provide sufficient evidence to create a genuine issue of material fact that the use qualifies as experimental. The ultimate burden, however, remains on the challenger to prove by clear and convincing evidence that the non-experimental use was public under § 102(b). *Id.*

With these burdens and legal standards in mind, this court agrees with the district court and the parties that no material facts relating to the public use bar are in dispute. The record shows that PHC hemihydrate was in public use before the critical date of the '723 patent. Specifically, SmithKline placed PHC hemihydrate in public clinical trials in the United States in May 1985. The critical date under § 102(b) for the '723 patent is October 23, 1985. Moreover, SmithKline administered PHC hemihydrate to patients without any apparent confidentiality restrictions on the patients or the administering physicians. SmithKline does not question the public disclosure of its clinical trials. Rather, SmithKline asserts that the clinical trials constitute an experimental use negating the apparent public use. In SmithKline's own words, the purpose of the clinical trials was "to establish that [PHC hemihydrate] actually worked (and was safe) as an antidepressant."

[14] Taking the facts in the light most favorable to SmithKline, this court assumes that the clinical trials were subject to satisfactory controls and otherwise properly conducted to fulfill their intended purpose--namely, to establish the efficacy and safety of PHC hemihydrate as an antidepressant drug for humans. The determinative inquiry in this case is whether SmithKline tested the invention of the asserted claim. "[T]esting or experimentation performed with respect to non-claimed features of the device does not show that the *invention* was the subject of experimentation." *W. Marine Elecs., Inc. v. Furuno Elec. Co.*, 764 F.2d 840, 847 (Fed.Cir.1985). In other words, an experimental use only negates a statutory bar when the inventor was testing claimed features of the invention. ***1318***In re Theis*, 610 F.2d 786, 793 (CCPA 1979) ("It is settled law that ... [an] experimental sale ... does not apply to experiments performed with respect to non-claimed features of an invention."); *LaBounty Mfg. Inc. v. U.S. Int'l Trade Comm'n.*, 958 F.2d 1066, 1074 (Fed.Cir.1992); *In re Brigance*, 792 F.2d 1103, 1109 (Fed.Cir.1986).

Indeed the Supreme Court case that created the experimental use negation, *City of Elizabeth*, 97 U.S. at 126, acknowledged the purpose of this doctrine: "The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as such a [public] use." In other words, the doctrine extends to experimentation on the claimed invention to bring it to perfection. The negation does not extend beyond the claimed invention or beyond the purpose of perfecting the invention. *See, e.g., In re Smith*, 714 F.2d 1127 (Fed.Cir.1983) ("[E]xperimental use ... does not include market testing").

[15] This court has already defined the invention of claim 1 as the PHC hemihydrate compound without further limitation regarding efficacy, commercial use, or pharmaceutical viability. SmithKline itself espouses that proper claim construction. With that definition of the invention in mind, however, clinical trials designed to establish the efficacy and safety of the compound as an antidepressant for FDA approval are not experimental uses of that claimed invention. In other words, the claim covers the compound regardless of its use as an antidepressant. The antidepressant properties of the compound are simply not claimed features. Consequently, the clinical tests, which measured the efficacy and safety of the compound as an antidepressant, did not involve the claimed features of the invention. The 1985 clinical tests, therefore, do not qualify as an experimental use to negate the statutory bar.

In making this ruling, this court is aware of cases that acknowledged an experimental use negation when the testing did not focus on an expressly claimed feature. *See EZ Dock*, 276 F.3d at 1353; *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1320, 1324 (Fed.Cir.1996); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 550-51 (Fed.Cir.1990). To some extent, this apparent confusion arises from a separate requirement of

patent law to test an invention for utility, i.e., to show that it works for its intended purpose. *See* Scott v. Finney, 34 F.3d 1058, 1061 (Fed.Cir.1994). This court has noted the potential overlap of utility and experimental use testing. *EZ Dock*, 276 F.3d at 1352. As suggested by their different origins and purposes, however, utility testing (reduction to practice) and experimental use testing are not synonymous.

Testing to reduce an invention to practice shows completion of an invention and establishes its utility. *See, e.g.*, Holmwood v. Sugavanam, 948 F.2d 1236 (Fed.Cir.1991). The focus is on whether the totality of the testing at the relevant time period was sufficient to prove an actual reduction to practice of the invention. *See* Scott, 34 F.3d at 1061-62. Experimental testing, on the other hand, negates evidence that an inventor has fatally postponed filing beyond a bar date. *See* City of Elizabeth, 97 U.S. at 126. Here, the focus is on whether the specific testing in question was necessary to reduce the claimed invention to practice. That is, after the invention is reduced to practice, further testing will not qualify as experimental use for purposes of negating a bar under § 102(b). *See* Continental Plastic Containers v. Owens Brockway Plastic Prods., 141 F.3d 1073, 1079 (Fed.Cir.1998) ("The policy behind experimental use negation is to give the inventor ***1319** an opportunity to reduce the invention to practice.... Thus, experimental use can not occur after a reduction to practice") (citations omitted).

Due to these different origins and purposes, the narrower experimental use negation does not extend beyond perfecting claimed features. In any event, even the cases above that acknowledge experimentation on features beyond those expressly claimed remain faithful to these strict limits of the experimental use negation. Each of those cases permitted testing to negate the bar when the experimentation improves or verifies a feature inherent in the express claims of the invention.

In *Manville,* for example, the claimed invention covered a light pole for highways that maintenance workers could lower for repairs. *See* 917 F.2d at 547-48. At the outset, this court decided *Manville* on the basis that the applicant retained the invention confidential and at no time placed it in the public domain. *Id.* The purported experimental use tested the illuminating device under severe weather conditions. Neither party asserted that this experimentation exceeded the literal scope of the claims, probably because the use occurred in a remote Wyoming rest area not yet open to the public at the top of a 150-foot pole. Indeed this court noted: "Manville did nothing to lead the public to believe that its iris arm invention was in 'the public domain.' " *Manville*, 917 F.2d at 549. In other words, the use was either not public or properly confidential. This court also noted: "Manville marked its design drawing with a confidentiality notice." *Id.* To the limited extent that this case also relied on the experimental use negation, this court explained: "[D]urability in an outdoor environment is inherent to the purpose of the invention." *Id.* at 551. Thus, the experimentation verified features inherent in the claimed invention.

In *Seal-Flex,* the claimed invention covered an all-weather activity mat (or track). *Seal-Flex*, 98 F.3d at 1320-21. The patentee alleged that the product it sold was not the completed invention because it was still being tested for its performance in harsh weather conditions. *Id.* At the outset, it is significant to note that this court decided *Seal-Flex* under standards for public use overruled by *Pfaff.* Therefore, this court weighed a "totality of circumstances" that no longer apply. *Id.* at 1322-23. Again, the parties did not raise the issue of limiting testing to claimed features. Like the *Manville* case, however, the scope of the claimed invention in *Seal-Flex* carried the inherent implication of performance in severe weather conditions. It was an all-weather track. *Id.* at 1324. Thus, the experimentation again focused on features inherent to the claimed invention. Importantly, this court in *Seal-Flex* did not affirmatively find that there was no on-sale bar under § 102(b) or that the activities constituted an experimental use. Rather, this court vacated the district court's summary judgment and remanded the case. *Id.*

In *EZ Dock,* the claim covered a "floating dock." *EZ Dock*, 276 F.3d at 1348. The testing involved the dock's performance in rough, choppy water. *Id.* at 1353. Although the claim did not have an express "choppy water" limitation, the claim language "floating dock" carried the implication that the invention must perform in rough water. Thus, again, the experimentation verified or improved a feature inherent to the claimed invention. Again, the court vacated the summary judgment of invalidity and remanded for determination of the on-sale bar and experimental use issues. *Id.* at 1353-54. In sum, this court has remained faithful to the strict requirements of the experimental use negation by limiting it to testing to perfect claimed features, or, in a few instances, testing to ***1320** perfect features inherent to the claimed invention.

In this case, SmithKline's experimentation does not fit within the rule limiting the negation to tests on claimed features. *See In re Theis,* 610 F.2d at 793. In connection with the claim interpretation issue, SmithKline strenuously argues that nothing in the claim language, the specification, or the prosecution history indicates that the scope of claim 1 implicates any intended commercial significance or medical purpose. In fact, the claim does not carry any implication of commercial significance or medical purpose. While SmithKline benefits from the breadth of the meaning of its claim, that claim does not require testing tailored to ascertain the safety and effectiveness of a particular use. Thus, testing the medical efficacy and viability of PHC hemihydrate is not testing the claimed features of the structural invention in claim 1.

SmithKline's assertion that the clinical tests constituted an experimental use of the invention of claim 1 is inconsistent with its claim construction position. This court also notes that these same clinical trials may serve to negate a public use bar with regard to the inventions claimed in the more specific claims of the '723 patent. Only claim 1, however, is before the court in this appeal. Nothing in the language of claim 1 can reasonably be read to carry an implication that the claimed compound will be used as an anti-depressant, or even a pharmaceutical for that matter. Because claim 1 covers the compound without further limitation, the invention of claim 1 was reduced to practice when that compound was first manufactured. Its efficacy as an anti-depressant is irrelevant to that determination.

Accordingly, a patentee should understand that testing the properties, uses, and commercial significance of a compound claimed solely in structural terms may start the clock under § 102(b) for filing a claim that is not limited by any property, commercially significant amount, or other use of the compound. Because these clinical trials tested only the safety and efficacy of PHC hemihydrate as an antidepressant, those trials were not an experimental use of the invention in claim 1. Consequently, this court determines that claim 1 of the '723 patent is invalid for public use under § 102(b) as a matter of law. This court reverses the district court's grant of summary judgment of validity in favor of SmithKline and reverses the district court's denial of summary judgment of invalidity in favor of Apotex.

Miscellaneous Issues

SmithKline also appealed the district court's decision to prevent SmithKline from pursuing its contributory infringement claim. In essence, that claim asserted that the ingestion of Apotex's PHC anhydrate tablet by a patient would result in conversion to the hemihydrate. In the interim, this court decided *Schering Corp. v. Geneva Pharmaceuticals, Inc.,* 339 F.3d 1373 (Fed.Cir.2003). In that case, this court determined that a compound claim was anticipated due to evidence that a prior art substance metabolized into the claimed compound upon ingestion by a patient. Recognition of the conversion process at the time of the prior art was not necessary to prove inherent anticipation. *Id.* at 1379-81. Thus, if SmithKline proved contributory infringement by showing that PHC anhydrate metabolizes into PHC hemihydrate upon ingestion, SmithKline may also have proved that PHC hemihydrate was inherent in the prior art. Nevertheless, because claim 1 is invalid for public use under § 102(b), SmithKline's appeal concerning its contributory infringement claim is moot.

Similarly, SmithKline's appeal of the district court's ruling that injunctive relief ***1321** under 35 U.S.C. § 271(e)(4) is within the district court's discretion is also moot. That ruling was not necessary for the district court's judgment below and is immaterial to the determination of this appeal. This court, therefore, does not address that issue in this opinion.

III.

In summary, this court reverses the claim construction of the district court and holds that claim 1 covers any amount of crystalline paroxetine hydrochloride hemihydrate without further limitation. Based on the factual findings of the district court, this court affirms the district court's finding that Apotex's PHC anhydrate product will infringe claim 1 under that broad construction. Notwithstanding that conclusion, this court holds, based on the undisputed facts, that SmithKline's clinical trials constituted a public use under § 102(b) rendering claim 1 invalid. Apotex is, therefore, not liable for infringing claim 1 of the '723 patent. This court affirms the district court's judgment.

COSTS

Each party shall bear its own costs.

AFFIRMED.

GAJARSA, Circuit Judge, concurring.

I concur in the court's judgment finding Claim 1 of

the '723 patent invalid, however, I reach the judgment by a different statutory provision. I would find Claim 1 invalid because it encompasses subject matter that is unpatentable under 35 U.S.C. § 101. [FN1]

> FN1. "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

I.

A. *Authority*

The question of patentability under Section 101 does not arise often, and a court's decision to raise it sua sponte is even less common. The centrality of patentable subject matter to the entire scope of the patent law suggests that there are times when such inquiries are critical. The Supreme Court established long ago that "the question whether the invention, which is the subject-matter in controversy, is patentable or not is always open to the consideration of the court, whether the point is raised by the answer or not." *Slawson v. Grand St. R.R.*, 107 U.S. 649, 652, 2 S.Ct. 663, 27 L.Ed. 576 (1882). *See also Richards v. Chase Elevator Co.*, 158 U.S. 299, 301, 15 S.Ct. 831, 39 L.Ed. 991 (1895). These precedents remain good law, though the courts have relied upon them infrequently. The policy that drove them, however, remains vibrant. Less than a decade after *Slawson*, in the context of an interference, the Supreme Court stressed that though

> [t]he parties to the present suit appear to have been willing to ignore the question as to patentability in the present case, and to have litigated merely the question of priority of invention, on the assumption that the invention was patentable. But neither the Circuit Court nor this court can overlook the question of patentability.

Hill v. Wooster, 132 U.S. 693, 698, 10 S.Ct. 228, 33 L.Ed. 502 (1890). In contemporary patent law, 37 C.F.R. § 1.641 specifically allows an administrative patent judge to raise the issue of patentability sua sponte as to claims designated to correspond to a count of an interference.

***1322** Beyond administrative proceedings, courts have found the occasional need to raise Section 101 issues sua sponte--even subsequent to the 1952 revisions to the Patent Act. At least three of our sister circuits, whose rulings on patent law prior to 1982 do not bind this court but retain persuasive value, raised Section 101 issues that the parties had not addressed. The Ninth Circuit announced that "it is the duty of the court to dismiss a patent infringement suit whenever it affirmatively appears that the patent is invalid." *Barkeij v. Lockheed Aircraft Corp.*, 210 F.2d 1, 2 (9th Cir.1954). According to the Second Circuit, "[e]ven were section 101 not raised by appellees, it was not error for the district court to consider it since it had the power to do so. Section 101 deals with the subject matter of patents and, as such, it is always open to the consideration of the court ..." *Howes v. Great Lakes Press Corp.*, 679 F.2d 1023, 1028 (2d. Cir.1982). And the Third Circuit explained that

> [i]t has been clear from an early date, that the court could dismiss a bill because the invention described in the patent was not patentable, even when no defense of invalidity was set up in the answer.... Accordingly, when a party brings suit on a patent alleging infringement, it is accountable for the validity of the patent....

Borden Co. v. Clearfield Cheese Co., 369 F.2d 96, 99-100 (3d. Cir.1966).

The Federal Circuit has independently raised Section 101 concerns without prompting from the parties at least once before. In *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed.Cir.1985), we considered a patent that the PTO had rejected as both anticipated under Section 102 and obvious under Section 103. *Id.* at 776. The district court reversed, and issued an order authorizing the Commissioner of Patents and Trademarks to issue the patent. *Titanium Metals Corp. v. Mossinghoff*, 603 F.Supp. 87, 91 (D.D.C.1984). The government appealed. The matter therefore reached this court on issues relevant to Sections 102 and 103, not to Section 101. We explained, however, that

> [t]he patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that what is sought to be patented, as determined by the claims, be new. The basic provision of Title 35 applicable here is § 101 ... The title of the application here involved is "Titanium Alloy," a composition of matter. Surprisingly, in all of the evidence, nobody discussed the key issue of whether the alloy was new, which is the essence of the anticipation issue....

Titanium Metals, 778 F.2d at 781. We concluded that "the decision and order of the district court holding that claims 1, 2, and 3 are directed to patentable subject matter and authorizing the issuance of a patent thereon were clearly erroneous and are reversed." *Id.* at 783. In other words, we

recognized that we could neither affirm nor reverse the district court's holdings under Sections 102 and 103 in a principled way without addressing the underlying erroneous assumption that the invention at issue met the requirements of Section 101. *See also Brassica Protection Prods. LLC v. Sunrise Farms (In re Cruciferous Sprout Litig.)*, 301 F.3d 1343, 1350 (Fed.Cir.2002) (characterizing as "common sense" *Titanium Metals'* rationale, including the injection of Section 101 into an anticipation analysis).

Both this court and the Supreme Court have recognized that there is a significant public policy interest in removing invalid patents from the public arena. In *Cardinal Chemical Co. v. Morton International, Inc.*, 508 U.S. 83, 100, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993), the Supreme Court reversed our practice of vacating findings of invalidity where the court found non-infringement ***1323** in light of the strong public interest in resolving questions of patent validity. In *Blonder-Tongue Labs., Inc. v. University of Illinois Foundation*, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971), the Supreme Court commented at length on the wasteful consequences of relitigating the validity of a patent after it has once been held invalid. In *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57-58, 93 S.Ct. 861, 35 L.Ed.2d 104 (1973), the Supreme Court ruled that the government, like patent licensees, could always challenge the validity of a patent in the course of prosecuting an antitrust action "to vindicate the public interest in enjoining violations of the Sherman Act." The Court cited numerous cases [FN2] as "sufficient authority" to support this holding, *id.*, which it saw as furthering a longstanding policy orientation: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly...." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234, 12 S.Ct. 632, 36 L.Ed. 414 (1892).

> FN2. *Telephone Cases*, 167 U.S. 224, 17 S.Ct. 809, 42 L.Ed. 144 (1897); *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 68 S.Ct. 525, 92 L.Ed. 746 (1948); *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173, 63 S.Ct. 172, 87 L.Ed. 165 (1942); *Edward Katzinger Co. v. Chicago Metallic Mfg. Co.*, 329 U.S. 394, 67 S.Ct. 416, 91 L.Ed. 374 (1947); and *MacGregor v. Westinghouse Elec. & Mfg. Co.*, 329 U.S. 402, 67 S.Ct. 424, 91 L.Ed. 380 (1947); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234, 12 S.Ct. 632, 36 L.Ed. 414 (1892); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969).

These decisions mirror our own recognition that "[p]ublic policy requires that only inventions which fully meet the statutory standards are entitled to patents." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1564 (Fed.Cir.1988) (citations omitted), and that "[t]here is a stronger public interest in the elimination of invalid patents than in the affirmation of a patent as valid." *Nestier Corp. v. Menasha Corp.-Lewisystems Div.*, 739 F.2d 1576, 1581 (Fed.Cir.1984). The best way to ensure that patents issue only for inventions in full compliance with the statutory standards is to allow "the validity of a patent, which was originally obtained in ex parte proceedings in the PTO, [to] be challenged in court." *Constant*, 848 F.2d at 1564.

My belief that this case warrants a sua sponte Section 101 inquiry therefore falls well within a long if somewhat sparse tradition, driven in part by concerns of public policy but grounded entirely in legal authority. Where, as here, the facts are both unusual [FN3] and undisputed, where the legal implication of these facts is clear, and where a consideration of fundamental aspects of law and policy is necessary to maintain the integrity of the patent law, a sua sponte inquiry into the patentability of the claimed subject matter is appropriate.

> FN3. The district court's maze of alternative claim constructions and theories finding Apotex not liable for infringement, plus the theory added by the majority, attest to the unique circumstances of this case. The district court's opinion, and in particular its attempt to introduce a novel equitable defense, *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1043-45 (N.D.Ill.2003) ("*SK II* "), strongly imply that something "feels wrong" about holding an infringer liable for inevitable, spontaneous infringement. We therefore face a choice. We can either address the issue head-on and explain why an attempt to patent unpatentable subject matter leads to so many apparent anomalies, or we can try to contort the aspects of patent law raised by the parties in order to avoid those anomalies. I believe that the law is best served by adopting the straightforward approach.

B. *Claim Construction and Prior Use*

Before discussing my reasons for finding Claim 1 of the '723 Patent invalid for ***1324** claiming unpatentable subject matter, however, I do need to address a few preliminary matters. I agree with the majority that the "single crystal" theory [FN4] provides the only construction that is entirely consistent with the Claim 1's language claiming "crystalline paroxetine hydrochloride hemihydrate" ("paroxetine hemihydrate"). I also agree with the majority that the paroxetine hemihydrate "made" in Apotex's seeded manufacturing facilities through the natural conversion of the off-patent paroxetine anhydrate and water vapor present a prima facie case of infringement.

> FN4. The district court defined the "single crystal" theory of Claim 1 as encompassing: *all* manifestations of the hemihydrate, no matter how or where produced, or in what quantity relative to the mixture of which it is a part; even if the production was inadvertent, unavoidable though undesired, and wholly without benefit to the producer or detriment to SmithKline in the sense of cutting into SmithKline's market; and even if the amount is so tiny as to be beyond the limits of detection of any instrument present or foreseeable and the product in which it unexpectedly pops up does not compete with anything made or sold by SmithKline. *SK II,* 247 F.Supp.2d at 1026 (emphasis in original).

I agree with the district court, however, that SKB is entitled to summary judgment that the '723 patent is not invalidated by prior public use, *SmithKline Beecham v. Apotex Corp.,* 286 F.Supp.2d 925, 938 (N.D.Ill.2001) ("SK I"), because "the control [SKB] actually exercised over the trials was sufficient to demonstrate that the trials were in the nature of experimentation rather than mere commercial use," *id.* at 934, and because SKB's experiments designed to assess the product's efficacy as an antidepressant, *id.* at 932, were relevant to the '723 patent in the same way that the experimental use doctrine preserved the validity of the patents in our previous cases. *See Manville Sales Corp. v. Paramount Sys. Inc.,* 917 F.2d 544, 550 (Fed.Cir.1990); *Seal-Flex, Inc. v. Athletic Track & Court Constr.,* 98 F.3d 1318 (Fed.Cir.1996); *EZ Dock, Inc. v. Schafer Sys. Inc.,* 276 F.3d 1347 (Fed.Cir.2002).

In *EZ Dock,* for example, the patent at issue claimed a polyethylene floating dock--like the claim at issue here, a product claim. *Id.* at 1348. The district court determined that the patentee had offered the claimed dock for sale in the United States. more than one year before filing the patent application. *Id.* at 1350. We noted that though the defendant had presented a prima facie case against EZ Dock, EZ Dock's evidence could convince a jury that the sales were experimental. *Id.* at 1352. We explained that though the "experiments" did not test features actually claimed in the patent, an experimental use defense was still available because "[the inventor] testified that he sold the dock ... to determine whether it was capable of performing its intended purpose in its intended environment." *Id.* at 1353.

We noted that this application of the experimental use doctrine, like our earlier assessment of experimental use in *Manville,* 917 F.2d at 550, extended the notion of experimentation beyond features claimed explicitly in the patent to include the *intended purpose* of those features. *EZ Dock,* 276 F.3d at 1353. The majority notes this extension with approval, and attempts to distinguish the present matter from our precedent by focusing on reduction to practice. According to the majority, SKB's testing of paroxetine hemihydrate's performance as a human antidepressant was not necessary to reduce paroxetine hemihydrate to practice. The majority does not make clear, however, why testing a light pole's performance at illumination under severe weather conditions was necessary to reduce the ***1325** light pole to practice, *Manville,* 917 F.2d at 547-48, why testing an all-weather activity mat's performance in harsh weather was necessary to reduce the mat to practice, *Seal-Flex,* 98 F.3d at 1320-21, or why testing a floating dock's performance in rough, choppy water was necessary to reduce the dock to practice, *EZ-Dock,* 276 F.3d at 1353-54. In all four cases, the claims at issue were product claims that did not claim the tested features explicitly. In all four cases, the patentees possessed the claimed product in substantial enough form to test their products' performance at their intended functions. The majority does not explain why only one of these four patentees had reduced its claimed invention to practice sufficiently to preclude the experimental use doctrine. I see no principled grounds on which to distinguish this case from our precedent. *See Manville,* 917 F.2d at 550; *Seal-Flex,* 98 F.3d at 1324; *EZ Dock,* 276 F.3d at 1353. The district court was correct in finding that, under our precedent, the prior-use bar did not invalidate the '723 Patent. *SK I,* 286 F.Supp.2d at 938. The majority seems to be trying to reach an ultimate conclusion of invalidity while avoiding the road less traveled.

Nevertheless, because the district court misconstrued the claim, I cannot share its conclusion that Claim 1 is "valid against the various attacks on it made by Apotex." *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp.2d 1011, 1052 (N.D.Ill.2003) ("*SK II*"). Claim 1 of the '723 patent is invalid because it is broad enough to claim subject matter that is unpatentable under Section 101. The troubling implications of this impermissible breadth explain the various anomalies that engaged the district court. Under normal circumstances, patented products do not simply "appear" in ways that convert noninfringing products into infringing products.

The district court found as a matter of fact that paroxetine hemihydrate is an exception to this general rule. *SK II*, 247 F.Supp.2d at 1022-23. I agree with the majority that the record supports the district court's factual findings, and that these findings provide the appropriate background for our legal conclusions--specifically including the district court's findings concerning seeding and conversion.

II.

A. *Theory of Infringement*

Because the proper construction of Claim 1 follows the "single crystal" theory, SKB must prove that Apotex's product does and will continue to contain at least some hemihydrate. Though SKB's legal burden is only to prove infringement by a preponderance of the evidence, *S. Bravo Systems, Inc. v. Containment Technologies. Corp.*, 96 F.3d 1372, 1376 (Fed.Cir.1996), SKB nevertheless faces a significant challenge. As the district court found, Apotex wants to manufacture pure anhydrate; any hemihydrate present in its product is an undesirable impurity. *See SK II*, 247 F.Supp.2d at 1015, 1025, 1045. Both SKB and the district court explicitly rejected the possibility that the anhydrous and hemihydrous forms of paroxetine came into existence simultaneously, and that every batch of paroxetine ever manufactured (or that ever will be manufactured) contains at least trace elements of hemihydrate--an argument that would not only prove SKB's point about Apotex's product, but would also invalidate the '723 Patent as inherent in the prior art. *Id.* at 1025.

SKB's basic theory of infringement, which the district court recognized as establishing a prima facie case of infringement when applied to the single crystal construction, *id.* at 1043, rests upon two scientific principles that remain matters of controversy within the scientific community, ***1326** both as general phenomena and as applied to paroxetine: seeding and conversion. *See id.* at 1021-23. Under this infringement theory, the form of paroxetine discovered in the 1970s was, indeed, pure anhydrate; hemihydrate did not exist until late 1984.

> [SKB's expert] Dr. Bernstein testified that he was 'absolutely convinced' that no hemihydrate had existed before December 1984 ... Dr. Terence Threlfall, Apotex's expert on polymorphism, testified [that] Dr. Bernstein's absolute certainty ... is not tenable. No one knows when the hemihydrate form of paroxetine came into existence, although it is a reasonable inference that it did not exist in a detectable amount until then.

Id. at 1022. From that date forward, however, it was impossible to produce pure anhydrate in a "seeded" environment because even under normal climactic conditions, at least some of the anhydrate would "convert" to become hemihydrate.

> This process of 'seeding' the old with the new can be deliberate--that is, can be a method of manufacturing the new polymorph--or adventitious, a result of the fact that some of the crystals become airborne and 'contaminate' the laboratory or plant in which the old crystal is being manufactured.... [T]he seeds relevant to this case are seeds that cause one polymorph to convert to another and these seeds are crystals of the form to which conversion occurs. A single tiny crystal, constituting a single seed, might induce conversion.... The creation of the new polymorph is likely to make the laboratory or plant where it is produced seeded, with the result that efforts to produce the old polymorph may instead produce the new one, since it is the more stable form. In principle it should be possible to re-create the old polymorph, just by replicating the exact procedure by which it used to be created, only this time in a seed-free environment.... [I]n practice efforts to re-create old polymorphs do not always succeed, probably because the critical mass of molecules that is required to cause conversion is so minute....

Id. at 1020. SKB therefore argues that any paroxetine manufactured in a seeded environment must inevitably contain at least some hemihydrate, that this condition has only prevailed since some time in late 1984, and that Apotex's facilities have been or inevitably will become seeded.

> According to SmithKline, the BCI plant [in which Apotex manufactures anhydrate] is seeded with hemihydrate crystals because it was there that Apotex, exercising the broadened experimental-use privilege conferred by the Hatch-Waxman Act, used and made hemihydrate in the course of developing its anhydrous product.

Id. at 1024.

B. *Findings of Fact*

SKB's proof supporting this theory must rest upon factual demonstrations. As an appellate court, we accept all facts found by the district court unless they are clearly erroneous. *Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1357 (Fed.Cir.2001). The district court, however, stated its most significant finding as an hypothesis:

> The conflicting testimony of Bernstein ... on the one hand and of Threlfall on the other can largely be reconciled on the following hypothesis: while the presence of hemihydrate seeds in a batch of anhydrate is likely, provided the ambient humidity and temperature are no lower than is normal in the temperate zone, to produce conversion within a short time, once the amount converted reaches a few percent of the mixture further conversion is unlikely without substantially greater humidity, temperature, or pressure.

***1327** *SK II*, 247 F.Supp.2d at 1022-23. Findings of fact stated as hypotheses pose particularly challenging problems for appellate courts. Did the district court accept this hypothesis as a fact upon which legal arguments and conclusions can rest, or was the district court merely trying to make sense of the scientific testimony that the two experts proffered?

The district court's own legal conclusions make it clear that the court accepted them as facts, by stating, for example, that "[Apotex's] BCI plant *is* seeded as a result of the mid-1990s experiments," *id.* at 1032 (emphasis added), and that "the anhydrate as it proceeds through the process [at the BCI plant] will at several junctures be exposed to air that contains enough water molecules to permit conversion of anhydrate to hemihydrate." *Id.* These statements make sense *only* if the district court found that both seeding and conversion are valid scientific facts, at least as applied to paroxetine for the purposes of this case.

The district court's understandable hedging of its language when dealing with controversial scientific theories nevertheless led it to definitive factual conclusions: "BCI *probably* will be 'making' at least some hemihydrate crystals and therefore infringing, at least prima facie, patent 723 if claim 1 is interpreted to cover single crystals of the hemihydrate." *Id.* (emphasis added). "Some conversion from anhydrate to hemihydrate *is likely* to occur in a seeded facility in which the anhydrate is exposed to air; BCI's plant is seeded; and the anhydrate manufactured there is exposed to nondehumidified air before it leaves the plant." *Id.* (emphasis added). But in concrete syllogistic conclusion, "[t]his evidence *is sufficient to support an inference* that BCI will be making at least tiny amounts of the hemihydrate if it is permitted to manufacture the anhydrate." *Id.* (emphasis added).

The district court therefore found, as a matter of fact, that paroxetine anhydrate in a seeded environment characterized by normal climactic conditions *can* convert itself spontaneously into paroxetine hemihydrate. *Id.* The district court further found that SKB had met its burden of proving, by a preponderance of the evidence, that such conversion *was inevitable* at Apotex's BCI manufacturing facility. *Id.* at 1042-43.

The district court next turned to consider Apotex's defenses. "If ... claim 1 is valid and will be infringed ... by a single crystal of hemihydrate ... [then] Apotex has a complete affirmative defense that SmithKline is the cause of the infringement." *Id.* at 1052. This conclusion makes sense only after a factual finding that Apotex's legal experimentation with Paxil [FN5] seeded the BCI plant. *Id.* at 1024. "Apotex cannot eliminate *all* crystals of hemihydrate; under a single-crystal interpretation of claim 1, [and] SmithKline is the sole cause of infringement." *Id.* at 1044 (emphasis in the original).

> FN5. Under the Hatch-Waxman Act, a generic drug manufacturer is allowed to experiment with a patented drug to prove that its planned product is bioequivalent to one already approved by the Food and Drug Administration (FDA). The district court viewed this statutory permission as an implied license, *SK II*, 247 F.Supp.2d at 1018, and attributed liability for the consequent seeding to SKB. *Id.* at 1044.

Finally, the district court explained that

> it is difficult, and in some cases it may be impossible (paroxetine hydrochloride hemihydrate may be one of those cases--no one knows), to destroy all the seeds in seeded premises.... Dr. Bernstein testified that if Apotex, desperate to avoid a charge of infringement built a new plant in Antarctica where no hemihydrate seeds had ever been and started manufacturing anhydrate there, and a ***1328** depressed worker in the plant dropped a Paxil on the floor, the result might be to seed the plant and make it impossible from then on to

produce pure anhydrate there.
Id. at 1020-21.

In short, the district court made four critical factual findings: (1) Hemihydrate crystals did not exist before their first emergence in an SKB laboratory in late 1984, *id.* at 1025; (2) Hemihydrate seeds spread easily, and increasingly large parts of the environment are becoming seeded, *id.* at 1020-21; (3) Under normal climactic conditions in a seeded environment, at least some anhydrate crystals will convert spontaneously to become hemihydrate crystals, *id.* at 1022-23 and (4) Apotex's manufacturing facilities have been seeded, *id.* at 1024.

III.

A. *Public Notice*

These findings of fact highlight the unique challenge that the infringement analysis of the '723 Patent poses: infringing matter has an unusual tendency to "appear" even where it is unwanted. Such a spontaneous appearance of a patented product vitiates the public notice function of patents. *See id.* at 1028. Under normal circumstances,

> one of ordinary skill in the art should be able to read a patent, to discern which matter is disclosed and discussed in the written description, and to recognize which matter has been claimed. The ability to discern both what has been disclosed and what has been claimed is the essence of public notice. It tells the public which products or processes would infringe the patent and which would not.

PSC Computer Prods. v. Foxconn Int'l, 355 F.3d 1353, 1359 (Fed.Cir.2004). When the claimed product can be "made" via the spontaneous conversion of a noninfringing product into an infringing one, adequate notice is impossible-- even if the claimed product was initially synthesized in a laboratory.

Long before 1952, when Section 112 formalized the modern written description requirement, the Supreme Court observed that:

> Whoever discovers that a certain useful result will be produced, in any art, machine, manufacture, or composition of matter, by the use of certain means, is entitled to a patent for it; provided he specifies the means he uses in a manner so full and exact, that any one skilled in the science to which it appertains, can, by using the means he specifies, without any addition to, or subtraction from them, produce precisely the result he describes. And if this cannot be done by the means he describes, the patent is void. And if it can be done, then the patent confers on him the exclusive right to use the means he specifies to produce the result or effect he describes, and nothing more.

O'Reilly v. Morse, 15 How. 62, 119, 14 L.Ed. 601 (1853). The Supreme Court further explained that

> [a]ccurate description of the invention is required by law, for several important purposes: 1. That the government may know what is granted, and what will become public property when the term of the monopoly expires. 2. That licensed persons desiring to practice the invention may know during the term how to make, construct, and use the invention. 3. That other inventors may know what part of the field of invention is unoccupied.

Bates v. Coe, 98 U.S. 31, 39, 25 L.Ed. 68 (1878). While these pre-1952 cases may not apply directly to the modern written description requirement of Section 112, they do demonstrate the longstanding centrality ***1329** of the public notice function to patent policy.

Paroxetine hemihydrate forces us, for the first time, to confront the requirement that "a patentee specify in a manner so full and exact, that any one skilled in the science to which it appertains, can, by [*avoiding]* the means he specifies," *O'Reilly*, 15 How. at 119, 14 L.Ed. 601, *avoid producing the claimed product.* Otherwise, there will be no way for "other inventors [to] know what part of the field of invention is unoccupied." *Bates*, 98 U.S. at 39. Effective notice is impossible if a natural physical process can convert a noninfringing product into an infringing one.

The district court was correct in concluding that Claim 1 of the '723 patent, subject to the proper single crystal construction, fails to provide suitable notice. *SK II*, 247 F.Supp.2d at 1028, 1052. A paroxetine anhydrate manufacturer, such as Apotex, could exert reasonable efforts to manufacture only products already in the public domain, could direct its entire production process toward developing only products that scrupulously respected all patent rights, and could nevertheless infringe because a natural physical process acting upon its legitimate anhydrous product "made" new hemihydrous crystals that Apotex then "sold" to the public. "Apotex has tried to prevent conversion of its product to the patented form and a principal issue in this case is whether it has succeeded; there is no suggestion that Apotex *desires* conversion." *SK II*, 247 F.Supp.2d at 1015 (emphasis in original).

Were we to nevertheless hold Apotex liable as an

infringer of Claim 1, we would effectively remove a valuable public-domain antidepressant, paroxetine anhydrate, from the market, and likely motivate potential inventors of superior grades of paroxetine to refocus their efforts elsewhere. This result is inconsistent with patent policy and--more importantly for the purposes of this court--it is incompatible with patent law. We would be holding valid a patent incapable of serving its important public notice function.

Claim 1 therefore cannot be held valid. But the failure of notice is a consequence of its invalidity, not the source of it. We must consider whether or not the '723 patent covers only patentable subject matter. *See Slawson,* 107 U.S. at 652, 2 S.Ct. 663.

B. *Patentable Subject Matter*

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore ..." 35 U.S.C. § 101. The Supreme Court has interpreted this statutory range of patentable subject matter to be quite broad, but hardly universal. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty,* 447 U.S. 303, 308, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980). That wide scope nevertheless excludes laws of nature, natural phenomena, and abstract ideas. "Such discoveries are 'manifestations of ... nature, free to all men and reserved exclusively to none.' " *Id.* at 309, 100 S.Ct. 2204, (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130, 68 S.Ct. 440, 92 L.Ed. 588 (1948)). *See also Diamond v. Diehr,* 450 U.S. 175, 185, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981); *Parker v. Flook,* 437 U.S. 584, 589, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." ***1330***Gottschalk v. Benson,* 409 U.S. 63, 67, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972). A single standard applies to product claims and process claims alike. *Id.* "[W]hether patents are allowable for [challenged subject matter] is not a matter of discretion, but of law.... Either the subject matter falls within Section 101 or it does not." *Animal Legal Def. Fund v. Quigg,* 932 F.2d 920, 929-30 (Fed.Cir.1991). And as a matter of law, the critical distinction guiding all Section 101 inquiries into the patentability of subject matter is that human-made, or synthetic, products or processes are patentable, while products and processes of nature are not. *See Chakrabarty* at 313, 100 S.Ct. 2204; *J.E.M. AG Supply v. Pioneer Hi-Bred Int'l,* 534 U.S. 124, 130, 122 S.Ct. 593, 151 L.Ed.2d 508 (2001).

The district court found as a matter of fact that at some point, likely in late 1984, something occurred in SKB's laboratories that gave rise to two new phenomena simultaneously. *SK II,* 247 F.Supp.2d at 1021-22. The first was a synthetic crystal later named paroxetine hemihydrate, *id.,* ostensibly a patentable human-made invention under *Chakrabarty.* The second was a natural physical process whereby paroxetine anhydrate (a pre-existing synthetic crystal that today is in the public domain) could, under normal climactic conditions and with no human intervention, bond with water molecules and convert itself into paroxetine hemihydrate, *SK II,* 247 F.Supp.2d at 1021-22, ostensibly an unpatentable, newly discovered natural process under *Chakrabarty.*

This distinction between the synthetic product and its natural "reproduction" process is subtle, but critical. Paroxetine hemihydrate is not the first invention to blur the line between a natural process and a synthetic product, nor is it the first to engender confusion in the patent law. In the Nineteenth Century, the conflation of the natural acoustical principles of telephony with the invention of telephone equipment gave rise to massive litigation. *See Telephone Cases,* 126 U.S. 1, 8 S.Ct. 778, 31 L.Ed. 863 (1888). In disentangling this complex patent litigation, the Supreme Court noted that:

> In one of the cases on appeal ... the court says: "There can be no patent for a mere principle. The discoverer of a natural force or a scientific fact cannot have a patent for that." But it proceeds to make this exception nugatory by confounding the natural process (or scientific fact) with the invented process for working the apparatus; sustaining the patent for the last upon a construction which blindly sweeps in the first.

Id. at 270-71, 8 S.Ct. 778. The '723 patent similarly confounds the scientific fact of paroxetine conversion with the invented product of paroxetine hemihydrate--and SKB similarly asks us to "sustain[ ] the patent for the last upon a construction which blindly sweeps in the first." *Id.* We should not only decline to do so, as the majority has and as the district court did in the alternative, but we should be clear about both the character and the implications of the underlying request.

Paroxetine hemihydrate is presumably a synthetic compound, created by humans in a laboratory, never before existing in nature, that is nevertheless capable of "reproducing" itself through a natural process. *SK II*, 247 F.Supp.2d at 1022-23. This crystalline compound raises a question similar to one that might arise when considering the invention of a fertile plant or a genetically engineered organism, capable of reproduction, released into the wild. Consider, for example, what might happen if the wind blew fertile, genetically modified blue corn protected by a patent, from the field of a single farmer into neighboring cornfields. The harvest from those fields would soon contain at least some patented blue corn mixed in with the ***1331** traditional public domain yellow corn--thereby infringing the patent. The wind would continue to blow, and the patented crops would spread throughout the continent, thereby turning most (if not all) North American corn farmers into unintentional, yet inevitable, infringers. [FN6] The implication--that the patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented blue stalks--cannot possibly be correct. The underlying question that engaged the district court, and that led it to develop numerous alternative holdings, is *why* this implication is incorrect.

> FN6. Although intent is not a factor in determining infringement, public notice is required as a predicate to the validity of a patent. *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1570 n. 2 (Fed.Cir.1996). The hypothetical causes unavoidable infringement even in situations where the public would, in good faith, want to avoid infringing.

At oral argument, when faced with this hypothetical, SKB expressed its belief that such a blue-corn patent would be "very strong." Such a belief is misplaced. The implicit concept of "inevitable infringement" stems from the inevitable failure of the patent to provide public notice--which, in turn, stems from the inherently unpatentable nature of the claimed subject matter.

This Section 101 problem therefore brings us full circle, back to the impossibility of public notice. Under normal circumstances, inventors other than the patentee will understand how to avoid infringing a patent by avoiding the claimed product. Because products, such as our hypothetical blue corn or SKB's paroxetine hemihydrate, that can be "made" through a natural process of spontaneous conversion imply inevitable infringement, no combination of claim language and written description could possibly teach even one skilled in the art how to avoid infringement. It is unsurprising that a requirement considered so trivial for most patentable products that we are content to let it remain implicit, namely a lesson in infringement avoidance, is effectively impossible for subject matter unpatentable under Section 101. In short, patent claims drawn broadly enough to encompass products that spread, appear, and "reproduce" through natural processes cover subject matter unpatentable under Section 101--and are therefore invalid.

C. *Invalidity*

Technological advances have forced this court, our predecessor court, and the Supreme Court to consider the line between the natural and the non-natural--including such inventions as non-naturally occurring plants and bacteria--several times over the past few decades. *See, e.g., In re Bergy*, 596 F.2d 952 (CCPA 1979), *rev'd sub nom Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980); *Pioneer Hi-Bred Intl, Inc. v. J.E.M. Agric. Supply, Inc.*, 200 F.3d 1374 (Fed.Cir.2000), *affd.* 534 U.S. 124, 122 S.Ct. 593, 151 L.Ed.2d 508 (2001). Paroxetine hemihydrate now appears to be the first patent litigated that forces the courts to consider the patentability of products and/or processes launched in a laboratory and released into nature.

Despite the complexity of the issue, the analysis is straightforward. An invention synthesized for the first time in a laboratory is eligible for patent protection under Section 101. Processes for producing this synthetic product in the laboratory and/or for using this synthetic product may also be eligible for patent protection under Section 101. However, a natural reproduction process, whether sexual, asexual, part of a chain reaction, or a process of decay, is ineligible for patent protection under Section 101. *Chakrabarty*, 447 U.S. at 309, 100 S.Ct. 2204; ***1332***Funk Bros.*, 333 U.S. at 130, 68 S.Ct. 440. An item reproduced by such a natural process, whether an inorganic structure or a life form, must ipso facto be ineligible for patent protection under Section 101.

The Supreme Court has cited with approval the Congressional Record surrounding the adoption of the Plant Patent Act of 1930:

> [A] plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, *nor can it be reproduced by nature unaided by man.* ..." S.Rep. No. 315, supra, at 6; H.R.Rep. No.

1129, supra, at 7. Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. *Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204, 65 L.Ed.2d 144 (emphasis added). In its recent ruling confirming that hybrid plants are patentable subject matter under Section 101, the Supreme Court noted that "[h]ybrid plants ... generally do not reproduce true-to-type, i.e., seeds produced by a hybrid plant do not reliably yield plants with the same hybrid characteristics. Thus, a farmer who wishes to continue growing hybrid plants generally needs to buy more hybrid seed." *J.E.M.*, 534 U.S. at 128, 122 S.Ct. 593.

The principle unifying these statements about patentability made in 1930, 1980, and 2001 is that products capable of being "reproduced by nature unaided by man," *Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204, are not patentable subject matter under Section 101. Though the parties have not briefed this question directly, they and the district court have provided more than sufficient facts to obtain a dispositive and incontrovertible legal determination that Claim 1 of the '723 Patent is invalid under Section 101.

The '723 patent, correctly construed, claims every single crystal of paroxetine hemihydrate, including those crystals arising through natural conversion. The district court properly admitted SKB's proffered expert testimony about the scientific mechanism underlying natural conversion, *SK II*, 247 F.Supp.2d at 1019-20, under *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), and *General Electric v. Joiner*, 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997), weighed it in conjunction with contradictory testimony proffered by Apotex's experts, *SK II*, 247 F.Supp.2d at 1022, and concluded that at least some of Apotex's anhydrate would convert itself to hemihydrate. *SK II*, 247 F.Supp.2d at 1022-23.

These findings lead to an inescapable conclusion--a conclusion that the majority attempts to dismiss as a question of "scope," rather than of patentability. Had SKB claimed "*synthetic* or *non-naturally occurring* crystalline paroxetine hydrochloride hemihydrate," the claim would have covered only patentable subject matter, and Apotex would be entitled to a judgment of noninfringement. Had SKB explicitly claimed the crystals converted in Apotex's facilities, as either "the *natural process* of converting paroxetine anhydrate to paroxetine hemihydrate" or "crystalline paroxetine hydrochloride hemihydrate *arising through natural conversion*," unpatentability under Section 101 would be manifest; though the claimed matter would be a useful composition, it would be one that occurred in nature. *See Chakrabarty*, 447 U.S. at 309, 100 S.Ct. 2204; *Funk Bros.*, 333 U.S. at 130, 68 S.Ct. 440. By claiming simply "crystalline paroxetine hydrochloride hemihydrate" with no reference to how it was produced, SKB effectively claimed "crystalline paroxetine hydrochloride hemihydrate *whether non-naturally occurring or* ***1333** *arising through natural conversion*." Claim 1, as issued, therefore combines patentable and unpatentable subject matter, and is invalid under Section 101. The "confusion" to which the majority alludes should never arise because we cannot reach Section 102 unless the claimed matter can overcome the hurdle of Section 101.

Inventors wishing to claim products that can either be synthesized in laboratories or generated by natural processes may protect themselves by incorporating negative limitation terms like "non-natural" or "non-human" into the claims that they submit for examination. *See Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1329 (Fed.Cir.2003); *Animal Legal Def. Fund*, 932 F.2d at 923; *In re Wakefield*, 422 F.2d at 904. SKB made no such distinction. SKB, despite an early recognition of seeding and conversion, *SK II*, 247 F.Supp.2d at 1022, claimed all paroxetine hemihydrate crystals, including both those "born" of natural conversion without human intervention and those "made" in a laboratory through explicit human effort. SKB further demonstrated its claim to a possessory right in naturally occurring crystals by pursuing this litigation, and articulated this claim explicitly during oral argument.

IV.

The asserted breadth of Claim 1 makes sense only under the erroneous belief that patents may protect products spread and reproduced by natural processes, directly contradicting our well established understanding of the limits imposed by Section 101. Given current scientific trends, such a belief could easily lead to misdirected research investments, to inappropriately issued patents, and to a widespread in terrorem effect crippling entire industries whose artisans learn that even their best efforts to respect patent rights may not save them from liability as inadvertent, inevitable infringers. As the district court recognized, the notice function of patents is meaningless in such an environment, *SK II*, 247 F.Supp.2d at 1028. The lack of suitable notice could easily chill innovation, inquiry, experimentation, and

commercial development.

Though the majority's approach to invalidating Claim 1 of the '723 patent under Section 102(b) defuses these negative consequences with respect to paroxetine, it does so at the cost of creating unfortunate precedent that will complicate future considerations of the experimental use doctrine. It also fails to address the central anomaly that the district court identified. We do no one any favors by allowing this important question to remain open. We should announce, as a court, that the patent law does not sanction the concept of inevitable infringement--lest someone mistakenly believe that it does.

I would hold that because SKB's assertion of the single crystal theory provides the correct construction of Claim 1, the '723 patent claims paroxetine hemihydrate crystals reproduced by nature unaided by man-- unpatentable subject matter--and is therefore invalid under 35 U.S.C. § 101.

365 F.3d 1306, 70 U.S.P.Q.2d 1737

Briefs and Other Related Documents (Back to top)

- 2003 WL 23858872 (Appellate Brief) Corrected Brief for Defendants-Cross Appellants (Jul. 23, 2003)Original Image of this Document (PDF)

- 03-1313 (Docket) (Mar. 31, 2003)

- 03-1285 (Docket) (Mar. 11, 2003)

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